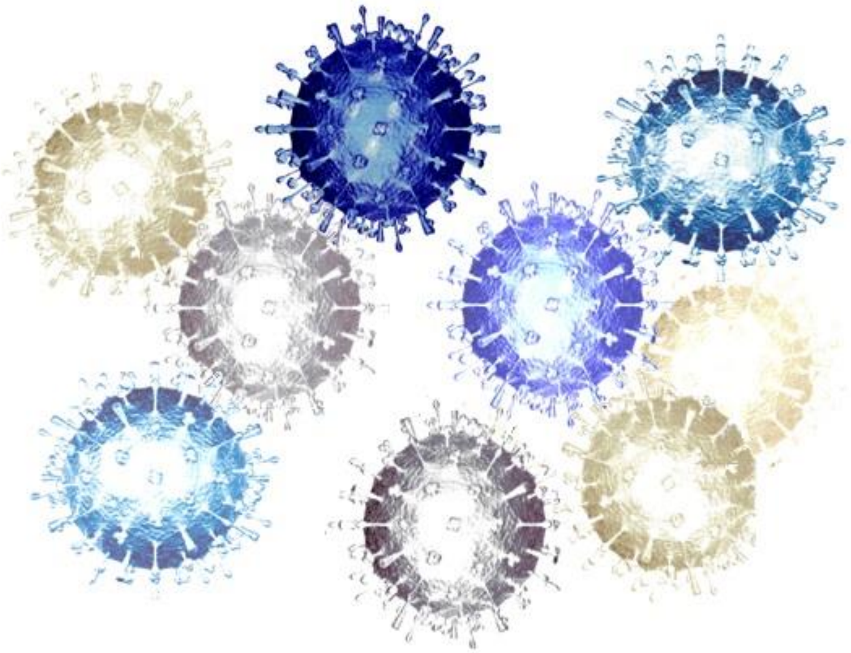
Mikhail Teppone

# Collection of transcripts of press conferences by WHO officers during the swine flu pandemic in 2009-2010 (26 April 2009 – 11 March 2011)



Shah Alam – Malaysia

2023

Dr. Margaret Chan:

"*On the basis of available evidence and these expert assessments of the evidence, the scientific criteria for an influenza pandemic have been met. I have therefore decided to raise the level of influenza pandemic alert from Phase 5 to Phase 6.*

*The world is now at the start of the 2009 influenza pandemic.*

*We are in the earliest days of the pandemic. The virus is spreading under a close and careful watch. No previous pandemic has been detected so early or watched so closely, in real-time, right at the very beginning*" [Geneva, WHO, June 11, 2009].

Disclaimers

The Collection was compiled by Mikhail Teppone.

This Collection was prepared in the course of research on Swine Flu Pandemic that was discussed in 2009-2010. The need for this collection is due to the fact that some of the web pages with the press briefings have been removed from the original sites and have been preserved only in the web archive.

The Collection has been prepared for research and education purposes to encourage further studies related to influenza pandemics that have occurred in the XXI century.

The Collection includes information that was found in the public domain only.

The Compiler declares there is no conflict of interests or any financial interest.

M. Teppone. Collection of transcripts of press conferences by WHO officers during the swine flu pandemic in 2009-2010 (26 April 2009 - 11 March 2011). – Shah Alam, Malaysia, 2023, 410 pp.
DOI: 10.13140/RG.2.2.29361.66409/3

# Contents

**Transcript ... Dates** PDF pp.

Transcript of the 26 April 2009 press Conference, Keiji Fukuda ... 4
Transcript of the 27 April 2009 press Conference, Keiji Fukuda ... 16
Transcript of the 27 April 2009 press Conference, Gregory Hartl ... 25
Transcript of the 28 April 2009 press Conference, Keiji Fukuda ... 31
Transcript of the 29 April 2009 press Conference, Keiji Fukuda ... 40
Transcript of the 30 April 2009 press Conference, Keiji Fukuda ... 47
Transcript of the 1 May 2009 press Conference, Gregory Hartl, and Dr Marie-Paule Kieny 52
Transcript of the 2 May 2009 press Conference, Dick Thompson, and Dr Mike Ryan ... 54
Transcript of the 3 May 2009 press Conference, Gregory Hartl, and Dr Peter Ben Embarek ... 62
Transcript of the 4 May 2009 press Conference, Gregory Hartl, and Dr Keiji Fukuda ... 68
Transcript of the 5 May 2009 press Conference, Gregory Hartl, and Dr Keiji Fukuda ... 77
Transcript of the 6 May 2009 press Conference, Gregory Hartl, and Dr Marie-Paule Kieny, 86
Transcript of the 7 May 2009 press Conference, Gregory Hartl, and Dr Keiji Fukuda ... 96
Transcript of the 8 May 2009 press Conference, Gregory Hartl, and Dr Sylvie Briand ... 103
Transcript of the 11 May 2009 press Conference, Gregory Hartl, and Dr Keiji Fukuda ... 109
Transcript of the 12 May 2009 press Conference, Gregory Hartl, and Dr Nikki Shindo ... 118
Transcript of the 13 May 2009 press Conference, Gregory Hartl, and Dr Sylvie Briand ... 124
Transcript of the 14 May 2009 press Conference, Gregory Hartl, and Dr Keiji Fukuda ... 130
Transcript of the 22 May 2009 press Conference, Gregory Hartl, and Dr Keiji Fukuda ... 139
Transcript of the 26 May 2009 press Conference, Gregory Hartl, and Dr Keiji Fukuda ... 150
Transcript of the 2 June 2009 press Conference, Gregory Hartl, and Dr Keiji Fukuda ... 158
Transcript of the 9 June 2009 press Conference, Dick Thompson, and Dr Keiji Fukuda ... 165
Transcript of the 11 June 2009 press Conference, Margaret Chan, Director-General, WHO 173
Transcript of the 7 July 2009 press Conference, Dr Keiji Fukuda ... 181
Transcript of the 13 July 2009 press Conference, Gregory Hartl, and Dr Marie-Paule Kieny 187
Transcript of the 6 Aug. 2009 press Conference, Dr Marie-Paule Kieny and Gregory Hartl 195
Transcript of the 24 September 2009 press Conference, Dr Marie-Paule Kieny and Gregory Hartl 206
Transcript of the 30 October 2009 press Conference, Gregory Hartl and Dr Marie-Paule Kieny 214
Transcript of the 5 November 2009 press Conference, Gregory Hartl, and Dr Keiji Fukuda 222
Transcript of the 12 November 2009 press Conference, Gregory Hartl, and Dr Nikki Shindo 234
Transcript of the 19 November 2009 press Conference, Dr Marie-Paule Kieny ... 239
Transcript of the 26 November 2009 press Conference, Kristen Kelleher, Dr Keiji Fukuda... 244
Transcript of the 3 December 2009 press Conference, Dr Keiji Fukuda ... 251
Transcript of the 17 December 2009 press Conference, Dr Keiji Fukuda ... 258
Transcript of the 14 January 2010 press Conference, Dr Keiji Fukuda ... 266
Transcript of the 11 February 2010 press Conference, Dr Keiji Fukuda ... 279
Transcript of the 18 February 2010 press Conference, Dr Keiji Fukuda ... 291
Transcript of the 24 February 2010 press Conference, Dr Keiji Fukuda ... 300
Transcript of the 29 March 2010 press Conference, Dr Keiji Fukuda ... 312
Transcript of the 14 April 2010 press Conference, Dr Harvey Fineberg ... 324
Transcript of the 19 May 2010 press Conference, Dr Harvey Fineberg ... 339
Transcript of the 2 July 2010 press Conference, Dr Harvey Fineberg ... 351
Transcript of the 10 August 2010 press Conference, Dr Margaret Chan, Dr Keiji Fukuda ... 369
Transcript of the 29 September 2010 press Conference, Dr Harvey Fineberg ... 379
Transcript of the 11 March 2011 press Conference, Dr Harvey Fineberg ... 402

# Transcript of the Press Conference undertaken with
# Dr Keiji Fukuda, Assistant Director-General ad. Interim
# for Health Security and Environment
# World Health Organization
# 26 April 2009

The first thing is that we will be giving regular meeting with the press on a daily basis and this is the first of those meetings. We know that the need for information is very great and we hope to help fill that gap by meeting with you every day. First I shall start by setting the context of what we are thinking about and what we are facing and then I will go into some of the specifics of what we know right now, and then we shall also provide some information about some of the actions which are being taken and then we shall take questions.

Many of you know that the world has been talking about and preparing for pandemic influenza for at least the past five years and there are a number of reasons for this. We know that influenza pandemics have occurred at least a couple of times each century and in the past five years we have been working very hard with our colleagues in many different countries because of a specific pandemic threat known as avian influenza or H5N1 and because of that many countries have been very focused on strengthening their defences for such a situation.

In the past several days, we have now heard about cases of infection in people caused by a different influenza viruses known as the swine H1N1 influenza virus. Influenza viruses have been know infect pigs for quite a long time and we know that every once in a while such viruses have caused infections in people. But right now in the current situation we appear to be in a situation where one of the swine viruses appears to be affecting significant number of people in at least a couple of different countries in different locations. This situation has raised questions about whether we are entering into a pandemic period.

Before we go further to what we know about this specific situation, let me just quickly review what we mean by a pandemic. A pandemic of influenza means that we have a new influenza virus to which most people in the world either have little immunity or no immunity and so this is different than our situation with regular influenza viruses. When we see such a new virus, if it has the ability to infect people and if it especially has the ability to move from person to person in a way that it is able to cause community outbreaks, large outbreaks of infection, then we certainly have the potential for the virus to spread from one country or one location to another.

Again, we have seen such occurrences a couple of times each century and so the question right now is whether we are in such a situation right now. Let us review the specifics:

One of the first things I want to caution everybody about is that we are in an evolving situation so we cannot be too focussed on numbers. These numbers can change quite rapidly as we know from any outbreak situation. So we have confirmed virus infections in the United States and in Mexico. Let me take the situations. In the United States as of the 25 April, yesterday, there were 11 laboratory- confirmed human cases of this swine influenza H1N1 virus. Seven of these infections in people occurred in California, two in Texas, two in Kansas. So we have 11 infections in total and I want to point out that all of these infections have been relatively mild, one of them did lead to a hospitalization for a brief period of time, but in general the infections have been mild.

Traditionally, as I mentioned these viruses have circulated in pigs but so far we have no evidence which suggests that these people were exposed to any sick pigs so we don't have any direct connect to swine right now. In addition preliminary virologic analysis of these viruses all show that they are basically the same virus when the genetic analyses were done. Other analyses continue right now, but basically we think the viruses that have been seen in California, and in Kansas and in Texas are the same virus.

We also know that in the United States, there have been other reports of illness, so these are being investigated. For example, we know that in New York City, there have been cases of influenza, eight cases of influenza that have occurred in students, and that specimens have been sent to the US Centers for Disease Control for confirmatory testing. In addition, we know that at 100 students have been reported to have influenza like illness.

So far, among these students, as far as we understand, the disease has been mild. Right now we await further confirmation from New York.

In Mexico, we know that there have been cases of respiratory disease and cases of pneumonia. And amongst these people some specimens have been sent out for testing, confirmatory testing. For example, 51 specimens from 51 people were sent to the public health laboratory in Winnipeg, Canada, and we know that 16 of these samples have been positive for this swine H1N1 influenza virus. Furthermore, we know that based on the work done in Canada and in the United States, that the viruses being seen in Mexico are essentially the same as the viruses that are being seen in the United States.

Testing is on-going and as this testing goes on we will have a better handle on all of the properties of these viruses.

Moreover we know that in Mexico there have been at least 1,000 cases of respiratory illness that were reported when the authorities have been studying this situation in April and among these cases there have been about 71 deaths. But I want to point out, these are cases of respiratory illness and we don't really know whether these cases represent a lot of swine 'flu infections or very few swine 'flu infections and so as investigations continue, we hope to have a better picture on this information.

One of the issues that all of this raises is what is the overall take on this situation and where are we. I think if look at the epidemiologic situation we have new influenza viruses that are being detected in a couple of different locations and we know that these are the same viruses and so there are a number of questions we have about the extent of spread of the viruses that is how far are, and to what extent they might be seen in the countries where they are being reported from now and whether they are being found in any other locations. There is a great deal of work being done by authorities in many different countries.

In terms of the virology of these viruses, or again what is known about the viruses themselves, they are swine influenza viruses, that is they are an animal influenza virus. However, they are different from other swine influenza viruses that have been described in the US and in Mexico. To that extent they do represent a new kind of swine influenza infection. So at this time it is fair to characterize our assessment of the situation as serious and WHO and the countries which are being affected by this, and certainly all countries are looking at this situation very seriously, but it is also clear that we are in a period in which the picture is evolving. It is also clear that we are in a period in which we have to be very careful to collect the best possible information.

We really need to understand a bit more about the epidemiology, we want to understand a bit more about the behaviour of these viruses and we want to understand to the extent that these viruses cause mild infections, and the extent to which these viruses can cause serious infections.

So in response to this situation, WHO has initiated several different actions. Let me go over some of them to give you an idea of the range of the activities underway.

On Friday (24 April) WHO activated its emergency response room, what we call the SHOC Room (Strategic Health Operations Centre) and what this allows us to do is be in contact simultaneously with countries, institutions, different authorities around the world, with the media, different partners and this allows us to bring together a lot of different functions which can handle an emergency situation. We have been in very close contact with many different governments as well as many other partners. For example we have been in contact with the UN, with non-governmental agencies, with industry, and we shall continue to work with all these partners so that everyone is as informed as possible and so that we can coordinate any necessary actions as well as possible.

The Mexican authorities did request that some assistance be provided and so WHO working with the governments in Canada, in the United States and in Mexico has helped to put together a number of people to go in to provide assistance to help clarify the epidemiologic situation as well as possible.

Another action undertaken by WHO was to convene the Emergency Committee of the International Health Regulations (IHR). This occurred yesterday (Saturday 25 April). The International Health Regulations are basically the overall public health architecture for how we deal with these large public health events or potential large public health events and basically it gives a way for all of the countries and authorities in the world to interact together, to coordinate their actions and to deal with health threats and this is one of the major improvements in modern day public health.

The role of the Emergency Committee is to provide advice and guidance to the Director-General of the World Health Organization. One of the issues that was discussed with the Emergency Committee in which they provided advice, was whether we are in what is called a Public Health Emergency of International Concern. Basically are we facing a situation which appears quite serious. I think that the Committee unanimously agreed that we are in such a situation and that it really warrants the utmost attention. So on the basis of that and the basis of the work and assessment being done by WHO and other colleagues, we have requested countries to help clarify this situation and to provide as much information as possible. So for example, we have asked all countries to increase their surveillance and watchfulness so that we can detect as quickly as possible how this virus may or may not be spreading.

One of the issues which was raised to the Committee, was whether we are in a situation where WHO should increase its pandemic phase. We are currently in Phase 3 and whether we should move it up to Phase 4. The Emergency Committee deliberated on this, and what they said is that we would like a little bit more information and a little bit more time to consider this. This is underway and more information is being collected and the Committee will be reconvened on Tuesday (29 April) unless there is additional information which indicates that we should meet earlier and right now the information does change on a fairly frequent basis. We will be mindful of that.

In addition, WHO is also undertaking a number of other actions. For example, we know that if this situation evolves, one of the questions that will come up very soon, is what is the availability of vaccines. We are already working with our collaborating centres, we have begun the preliminary work need to prepare influenza viruses for potential swine vaccine if we need it.

In addition, there has been a lot of work going on to make sure that we reduce the confusion as much as possible. For example, to produce a standard case definition which will be helpful both to the authorities looking for potential swine influenza cases as well as for the rest of us when we talk about what the situation is, so that we don't get disease mixed up with laboratory-confirmed cases and so on. In addition, the collaborating centres have been working very hard to produce the kinds of tests and reagents needed by other laboratories around the world so detect these infections. So there is a great deal of work going on so that we can as quickly detect and monitor the situation and do this as well as is possible.

That provides a broad overview of why we take the situation seriously, what the specific situation is based on the information we have at this time and some of the actions which have been initiated at this time. As you know from experience, situations evolve and we will continue to meet with you on a regular basis and provide the information as it becomes available to us. Let me stop there and we will take any questions.

Journalist - Canadian Press
You mentioned that reagents are being developed and that process is still underway. As a consequence, there are places that are finding influenza viruses which are probably going to turn out to be swine 'flu as the New York cases just confirmed. Can you tell us how many countries have reported to you that they have probable cases as a consequence of finding untypeable influenza viruses.

Dr Fukuda - I cannot right now give you the number, but we can find that out. We have been monitoring the media as well, and I know that there have been in the media in the last day or so reports of possible cases in places such as New Zealand and in the UK as well as I believe in Canada. But we know that some of these cases have been excluded, for example the person who was ill in the UK is known not to have swine influenza and so we await further information on the other cases.

Journalist: You said yesterday the Emergency Committee wanted more time, but to many people here in the real world it looks very much like does not fit the definition of Phase 3, and I am hearing from people in the infection control sector that this is really making life difficult for them. They don't know if they are going to 4, 5, 6, sometime in the next few days, and they don't know whether to stand up or not. Should they be operating under the assumption that this is probably a pandemic?

Dr Fukuda: I think that whenever we face any emergency situation there is of course a balance between the need to have a fair amount of information so that we feel that our decisions and our assessments are based on solid grounds. On the other hand, I think we are also mindful of the need for different groups to act and to make decisions. Now, if WHO goes ahead and makes a declaration that the phase has changed, then this is really a very serious signal to the world that they are to be initiating certain actions and really dusting off plans. Now I have no doubt that many countries are already taking these actions, but it does send a signal. We want to make sure that we are on pretty good solid grounds.

Right now we have cases occurring in a couple of different countries and in multiple locations, but we also know that in the modern world that cases can simply move around from single locations and not really become established, so one of the things for example is that we would like to have a little bit more information about the spread of these viruses and if it really indicates that it is taking hold in many different places. So I think a combination of information from different countries and from the countries and locations where the virus has been verified, it is the kind of information that the Committee is asking for. We will not wait for a very long time for such information to come in because we know that many different groups are waiting for this kind of decision. We have decided to wait and try and get a little more information so that the Committee can deliberate on this.

Journalist: Wall Street Journal: Just following on that, could you remind us of what the implications are of raising, should the pandemic alert to be raised to Phase 4. What would be set in motion, that makes it different from level 3 (in terms of actions). Secondly, you as an expert on influenza viruses, it is possible that we are at the early stages of a still mutating virus that could become even more potent. I ask this because the disease in some people has been very mild.

**Dr Fukuda:** First I think, let me clarify what a phase change means going from Phase 3 to Phase 4 and then the later phases potentially. Currently the world is in a phase or has been in the Phase 3 situation which means that we have seen potential pandemic viruses such as avian influenza infect people, in fact we have seen that virus infect people in many different parts of the world. However, those infections, by and large have been sporadic infections where single people get infected, or rarely it has caused infections in very small groups, so for example when parents or siblings have taken care of an ill family member we sometimes have seen situations of person to person transmission. If we go to Phase 4 because of the swine influenza virus, it basically means that we believe that the virus has significantly, or a potential pandemic virus has potentially shown that it is able to transmit from person to person and cause large outbreaks. This is a pretty big change from Phase 3 to Phase 4. If we go to Phase 5 and 6, that basically indicates without going into details, that the virus has shown the ability and is spreading around the world. So it is really a geographic spread around the world.

The change from Phase 3 to Phase 4 is an important change.

If we go from Phase 3 to Phase 4 you can see that on the website. There is a document indicating about the phases and potential actions that governments should consider, but what it does is that it sends a signal that governments should very strongly increase things such as surveillance, look at their pandemic preparedness, and begin to really assess seriously what steps they can take that if this should continue on to be a pandemic situation. And so those are some of the implications for going from one phase to another.

In terms of your second question, is it possible for this virus to mutate? So currently we cases we are mild and we see cases which appear to be quite severe, although again we don’t know the exact relationship of this specific swine 'flu viruses to the serious cases, you know we don't know how often it causes serious disease as opposed to mild disease. But none the less we see both of those things occurring right now.

Now influenza viruses as a group of viruses are just very prone to changing. They mutate easily, they evolve easily and so yes, it is quite possible for this virus to continue to evolve. So when viruses evolve, clearly they can become more dangerous for people, that is to cause more serious disease, or they are also able to mutate so they cause less serious disease and that is very difficult to predict. It is one of the things that we will watch for very carefully for the signs of evolution.

**Journalist, Kuwaiti News Agency**: Given the fact that President Obama was in Mexico just before the outbreak, is the Emergency Committee going to look into the possibilities of bioterrorism and my second point is why is there a big difference between the situation in Mexico and the United States? You have the death toll in Mexico - 71 - while in the United States, there are no deaths from this 'flu. Has the absence of a vaccine for this strain made your efforts over the past five years not up-to-date or they will not be useful or what do you think?

**Dr Fukuda:** Right now we have no evidence at all to suggest that we are dealing with bioterrorist action. We know from the past that pandemics occur and we know from the past that pandemic are caused by new influenza viruses, so right based on the analysis of the virus that we see, we have no signs we are dealing with purposeful action. However, as always we will continue to assess the situation, we shall continue to study these viruses and learn what we can.

In terms of the second question, why is there possibly such a big difference between what is going on in the US and Mexico in terms of the severity of illnesses. Here again it is very important for everybody to understand that the cases being reported from the US are laboratory confirmed cases of illness. In Mexico, we have a couple of different things being reported. We have both cases of disease being reported that we do not yet know are really due to this swine influenza virus, and we also have some laboratory confirmed cases. Right now it is very difficult to know whether we are seeing quite different situation in US and in Mexico. The typical picture for any influenza virus is that it causes both mild 'flu cases and severe 'flu cases and so again the picture is changing and there are very big gaps in what we understand about the clinical impact of this virus. This is one of the things that we will watch very, very carefully and keep you up-to-date on as our understanding develops.

In terms of the question of whether the absence of a vaccine over the past five years has made this work more difficult, one of the things that I did want to highlight is that I believe the world is really much, much better prepared than we have ever been for dealing with this kind of situation. This is for a couple of different reasons. In the past five years the world has spent a huge amount of effort, countries have worked very hard to assess the threat of avian influenza, they have worked very hard on pandemic preparedness planning and we have new tools such as the International Health Regulations in place.

We also have new defences in place, we have better surveillance, we have stockpiles of anti viral drugs that have been prepared at regions as well as by internationally in case of a pandemic situation. So if anything, I am really impress at how well the countries have handled this. The communications have been very good, the laboratory work has been conducted very fast, epidemiologic investigations always take longer, but information on the genetic sequences of viruses are now available in data bases for people or other scientists to see quickly. There are discussions going on among scientists around the world and so in many ways I would say the past five years has put us in the best possible position to handle this kind of situation so nothing has been wasted.

**Journalist, German Press Agency:** Is it possible that the WHO is working too slowly here, and that governments should actually be doing more besides monitoring the situation and reporting back. If so, what can governments be doing besides simply monitoring and reporting?

**Dr Fukuda:** I think that certainly governments do not necessarily wait for WHO to make recommendations before they do anything and in fact many governments are very proactively working on the situation now. So I think that this is a very high priority that we all have a better handle on the situation and so the information collection activities are critical. On the other hand I know that many governments are also looking at what their plans are if the situation escalates and what possible actions they may take. So I think the governments are being very active right now and they are certainly not being passive. Nonetheless, I think that they are looking to WHO for guidance and again because of that we are moving at a good clip, but we are wanting to make sure that we move in a way that the evidence really supports.

**Journalist, Associated Press:** Clarification about the virology of the virus. I was talking to a colleague of yours who said that the virus was entirely swine, but it has been described by CDC as having human/bird/swine elements. Could you clarify that? Secondly, if the virus turns out to be mild, is this going to be worse than the common cold?

**Dr Fukuda:** This virus appears to be a swine 'flu virus but one of the interesting things you know about influenza viruses is that the gene from influenza viruses can come from many different kinds of influenza viruses, so the internal genes of the virus that we are seeing now do come from multiple different sources but consistent with the kinds of influenza viruses that have been circulating in pigs for many years with two notable differences. Two of the genes appear to come from swine influenza viruses that have been circulating in Europe and in Asia and then the rest of the genes appear to be consistent with the kinds of genes found in viruses circulating in pigs in North America.

Somewhere along the line these genes combine to produce the virus that we are seeing now.

Now in terms of lethality, again I think we are too early in our investigations to be able to address the lethality of the virus. Clearly we are seeing reports of cases which are mild, and these are coming from the United States and we are also hearing reports about cases in Mexico, although it is a little a bit less clear how often these are associated with either fatal cases or serious illness cases. So at the start of a pandemic, one of the things that we try to do is get an assessment of the severity but it is important again to remember that the properties of 'flu viruses can change over time. They can go from mild to being more severe as time goes on and they can also move from being more severe to less severe over time. It is way to early right now to predict whether we might see a mild pandemic or a severe pandemic, but again we will keep you updated as we understand.

(The next part is unintelligible) both in humans and I am wondering if you are also aware of any studies in pigs or any pig deaths as a result of this virus. How are you studying the immunology of virus what are you looking at?

**Dr Fukuda:** Well right now the studies the studies themselves again are conducted by many scientific institutions and public health institutions which are involved in the investigations and so I think much of the emphasis right now is being devoted to characterizing what is the epidemiology of the situation as well as what are the characteristics of the viruses, which are available. What is the antigenic properties? What are the virologic properties and then there are some important questions related to whether antibodies produced by current seasonal vaccine may provide any protection against the swine flu virus. So there are a variety of studies like that being conducted and underway. So a combination of laboratory studies and epidemiologic studies.

**Journalist BBC:** You said that the situation in Mexico was unclear. I am just wondering if the deaths in Mexico - have you got a figure of ones you know where swine flu? Have you got a figure of those that weren't?

**Dr Fukuda:** Right now the authorities are working to clarify some of that information, I think that it would be very helpful again to know how often infections of these viruses do lead to death but at this point I'm not able to say that.

**Journalist, New York Times:** Couple of questions here and one has to do the semantics of calling this a swine influenza virus. If we have no evidence that it has caused any outbreaks in pigs and have no association there, is it causing confusion to call it a swine influenza virus is it more appropriate to call it a H1N1 and I realize that causes confusion because that is similar to the 1917/1918 one.

You said there was rapid communications but there is talk about delay in Mexico in terms of reporting or investigating these. What do we know about those delays and lastly do we know anything about when the deaths occurred in the cases that were the severe ones in other words could they be mild and suddenly turn lethal?

**Dr Fukuda:** Let me try to address these in terms of the semantics it is a little bit confusing but right now I would say that animal authorities will be looking at this situation in pigs. Right now we don't have any information on outbreaks, large outbreaks in pigs but their calling them swine influenza viruses comes from the genetic analysis of these viruses. So when you study them and you look at how they're constructed, they're constructed in the way that swine influenza viruses are as opposed to the human H1N1 viruses. So I think that this is an area which is quite easily going to lead to confusion because we have human H1N1 influenza viruses that are currently circulating around the world and we also have H1N1 viruses circulating in pigs and there different groups of viruses and then among those circulating in pigs you know the one we are talking about now appears to be different than the other H1N1 viruses in pigs so we will be very mindful to try to keep that confusion down. But I think it is fair to say that these are swine influenza viruses causing infections in people right now.

Having said that I think that one of the things to explain is that typically pandemic viruses start from animal viruses and in a sense they becomes humanized so animal viruses for whatever reason every once in awhile come over from the animal side or some other genes do and then they lead to infections in people and when they progress long enough they really become more human influenza viruses. And so in a sense that is what a pandemic is.

Now in terms of communications I think that personally the communications have been very open and very transparent in my time in public health I really have worked on a number of different outbreak investigations and I think that the communications and the willingness of the countries and authorities in this situation have really been exemplary they have been really good so no I can't characterize this as being slow.

And then in terms of the information about deaths again we are trying to clarify and get more information about that so I think that I can't really give a good description about the time of death and whether how the progression goes but we hope to be able to provide more of this kind of information as soon as we can and hopefully soon.

**Journalist CNN -** my first question is about stockpiling the Tami flu or the antivirals. Are you concerned about people who proactively might be trying to stockpile them privately or within communities and also are current supplies of the antivirals available and adequate? And how will the decision be made internally whether or not use whatever has been stockpiled by the World Health Organization and its affiliated organizations, that is one question.

Also I wanted to ask you about did anyone from Mexico indicate to the World Health Organization that they were having an outbreak of pneumonia as a respiratory illnesses when this started happening which appears to be at least as early as mid March. And if not wouldn't that be some kind of wouldn't that omission be considered potentially a breach of the protocol of reporting back to your Organization

And then finally just one more question about the transmission. After hearing reports about the New Zealand incidences, is it possible to get swine 'flu to contract it from simply flying on a plane and after you are exposed, how long after your exposure do symptoms actually develop as far as we know?

**Dr Fukuda:** These are good questions and a little bit wide ranging. In terms of Tami flu right now. WHO has some Tamiflu stocks which are available. These are about 5 million treatment courses and these have been developed and held both to assist in rapid containment operations if that were to be conducted but also to provide to countries in terms of assistance when it's needed. Now in addition to the stockpiles held by WHO, there are regional stockpiles and then there are national stockpiles of drugs in many different countries. Not all countries. And so right now certainly we have much more Tami alsotamivere immediately available then if we were to go back a few years ago. And in addition the manufacturer has worked hard to increase its manufacturing capacity so I think for the immediate period I would say that we are much better off than we have been in the past if this situation escalates and I think that the demand for antivirals clearly will also escalate and then this will require both the stockpiles probably increased production of this drug.

In terms of hoarding, yes I think that there is, this is something that we would definitely not encourage for people to go out and hoard the vaccines or hoard antiviral drugs but i think this again something that national authorities will be addressing with their countries in terms of updates.

Now the reporting of this issue was done I think in a timely manner by Mexico. Now in Mexico they were having the influenza season when these cases may have started, and so at that time of course they were a lot of respiratory disease cases occurring and these were secondary to the influenza viruses that we normally see. And so this is not the kind of activity that we would typically ask a country to report to WHO as being suspicious.

However when the authorities did notice that they were seeing increased pneumonia cases, and when they did notice that they were seeing an increase in serious pneumonia cases, then I think they took some very prudent actions which was to initiate investigations on their own and try to analyse the situation, figure out what going on they collected samples. They got them to they began the testing in their own laboratories and got them out to other confirmatory laboratories so I think that have done a really good job in doing what a country should do.

You know you investigate what is going on and then when there is something unusual or serious going on that is when this whole mechanism about the International Health Regulations really helps a handle.

Now in terms of what we know of about the incubation of this infection I think that right now we don't have enough information to talk about the specific incubation period of this virus nor the transmissibility of this virus. However if we look at influenza viruses in general, we know that the incubation period is typically about one to four days and we know that when people are not protected against influenza, that it is possible to catch influenza in any number of situations. This can be in families, in can be in schools it can be at work and it can be in an airplane, so it can occur in a variety of different locations.

**Journalist from Brazil:** Two questions. First of all how much is Latin America exposed in case for example it goes from level three to level four? If you could clarify whether the region is well prepared or not. And secondly we see today that Russia banned meat from Mexico, (pork meat of course), and Egypt is also checking on the meat. Is that something that needs to done?

**Dr Fukuda:** Let me address the second issue first because it is something I want to say very clearly. Right now we have no evidence to suggest that people are getting exposed or getting infected from exposure to pork or to pigs. Right now we have zero evidence to suspect that exposure to meat leads to infections.

Latin American countries as other countries around the world have been working to prepare themselves for a pandemic influenza. They have been very mindful of avian influenza and although avian influenza has not been a problem in Latin America certainly the governments have taken note of that. And so I think that the situation and state of preparedness may vary from country to country. But we have been dealing with avian influenza and the threat of pandemic influenza for the past few years and so we are better off than we were before but again this is country by country situation.

**Journalist from Reuters** - I wanted to check two things. Has the WHO sent officials to staff airports in Mexico or in other countries to facilitate health checks of arriving passengers? And secondly earlier on you mentioned the lab tests conducted in Winnepeg where 16 cases have proved positive. I just wanted to check where those samples had come from, I did not hear you clearly.

**Dr Fukuda:** WHO at the request of Mexico has initiated the sending out of experts to help the Mexican authorities in their investigations and in strengthening labs and so on. We are not specifically sending out staff to different countries to man airports and to do things such as checking passengers out at airports. In terms of the laboratory tests which were conducted in Winnipeg these were specimens which were received from Mexico.

Thank you.

# Transcript of Virtual Press conference with
# Dr Keiji Fukuda, Assistant Director-General ad. Interim
# for Health Security and Environment
# World Health Organization
# 27 April 2009

Thank you to all of you for having been so patient and having waited so long. I will without further due go over to Dr Keiji Fukuda, Assistant Director-General for Health Security and Environment for the World Health Organization. Dr Fukuda will tell you what has been decided today during the second Emergency Committee.

**Dr Fukuda:** Thank you Mr Hartl. Welcome everybody and thank you for attending this press briefing. Again, I apologize for the lateness of the hour but this press briefing necessarily follows the ending of the Emergency Committee meeting, which you are all ready to hear about. Now, as you know, tonight, WHO convened the second meeting of the Emergency Committee and at this meeting the Emergency Committee was asked to provide advice to the Director-General of the World Health Organization on three issues :

1) what was it advised on moving from pandemic phase 3, which is what we have been in, to pandemic phase 4;
2) should WHO start the process to develop the swine H1N1 vaccine and stop seasonal vaccine; and
3) what the temporary recommendations should the Director-General of WHO make.

Now, since these discussions and deliberations have been anticipated by many of you, what I will try to do, is walk you through them carefully one by one and then, we will have questions.

I do want to remind you that the 17:00 or 5 p.m. press briefings will continue. Again, this one is an extra press briefing held late because of the Emergency Committee meeting.

Based on the advice and the guidance of the Emergency Committee, the Director-General has decided on the following issues:

1) the pandemic phase alert should increase from phase 3 to phase 4;
2) given the current situation, the current focus of efforts should really be on mitigation efforts rather than trying to contain the spread of this virus, predominantly because this virus has already spread quite far, and at this time, containment is not a feasible operation;
3) the Director-General recommends not closing borders or restricting travel; however, it is prudent for people who are sick to delay travel and it is also prudent for returning travellers, who are coming back from any parts of the world and who have become ill, to seek medical attention in line with the guidance from their national authorities; and

4) the fourth decision is that the production of the seasonal influenza vaccine should continue at this time; however, WHO should also monitor the situation very carefully and should facilitate the process to develop a vaccine against this new swine H1N1 influenza virus.

So, let me walk you through these deliberations and these decisions one by one, and try to explain a little bit more about what they mean.

If we look at the move and the change from phase 3 to phase 4, what this can really be interpreted as is a significant step towards pandemic influenza, but also it is a phase which says that we are not there yet. In other words, at this time, we think that we have taken a step in that direction but a pandemic is not considered inevitable at this time. The situation is fluid and the situation continues to evolve and we will monitor that. What this means is that the disease patterns and the disease spread could change and we also know from much experience with influenza viruses, that the viruses themselves could change; and so in this overall situation as it evolves, there is careful monitoring, which we will do. Of particular importance for us and for other organizations in countries around the world, is really to monitor the spread of this virus and disease. Previously, yesterday, we had talked about increasing surveillance in all countries, but also when there are cases of illness that are due to this swine influenza virus, to document the symptoms, the clinical course, and the severity of the illness. Most importantly, to be very watchful and mindful beyond the look out for outbreaks such as community outbreaks and institutional outbreaks, which could be consistent with this virus.

The deliberations of the Emergency Committee and the decisions of the Director-General really reflect a lot of very careful and sober discussions on a number of important considerations. One of these considerations is that in looking at the overall epidemiological picture, the Emergency Committee unanimously felt that this was consistent with human-to-human transmission of this swine influenza virus. There is very little doubt about this. A second point is that the overall epidemiological picture appears to be consistent with the sustained human-to-human transmission. However, it was also felt that continued collection and analysis of more data on whether this is truly sustained transmission would be useful and would be important, and are to be analysed as data come in. Nonetheless, it was also felt that given the rapidly evolving situation, that it was important to send a strong signal to countries, that now is a good time to strengthen preparations for possible pandemic influenza, if it continues to evolve in that direction. Finally, the Committee was mindful that these cases being seen outside of Mexico have been mild. However, at the same time, looking at the laboratory-confirmed cases of the swine influenza in Mexico, it is also clear that a number of the people infected by this virus have had very severe illness.

Let me go on to the second decision, which was that really the efforts of countries should be to focus on mitigation of the spread of this virus rather than try to contain this virus. One of the main consideration in Phase 4 is a potential effort to try and stop this virus, which is normally called "containment" or "rapid containment". The Committee discussed this situation in depth and decided that, based on the analysis of the current situation and particularly because the virus is so widely spread – now being seen in Canada, in different locations in Canada, multiple locations in the United States as well as in Mexico, and then a late report today of an infection in Spain – that really this virus is too widespread to make containment a feasible consideration. What this means is that, focusing on mitigation is really an important focus of countries, and this really means trying to protect individuals, trying to protect populations and putting the actions and steps in place to do that against this swine influenza virus. For example, this means making sure that people have the information they need about this virus so that they can avoid infection if possible, and other steps to try and prevent infection.

A third issue that was discussed was that, in a decision by the Director-General, WHO does not recommend closing the borders and does not recommend restrictions of travel. Again, at this point, with the virus being widespread, from the international perspective, either closing borders or restricting travel would really have very little effect, if any effect at all, at stopping the movement of this virus. However, it would certainly cause a great deal of disruption for countries, and again, the focus on the safety of people and the safety of populations really means that there can be steps taken to try to reduce the chances of harm, but at this time, closing borders would not be helpful. So, again, this really emphasizes the importance of steps such as avoiding travel when you are sick, or if you become sick, or seeking medical attention, so that if you are infected by the swine influenza virus or any number of other infectious agents, you can be taken care of properly.

The last decision, and the last major discussion was on the vaccine issue. In here, it was felt prudent and important to continue the production of the seasonal vaccine at this time. The Emergency Committee was quite mindful of the fact that the influenza season is really kicking into gear in the southern hemisphere and that people develop serious illness from seasonal influenza viruses and that vaccination against these can be very important in preventing disease and death from seasonal influenza. However, the Committee was also very mindful of the H1N1 situation and the fact that we could be moving closer to pandemic influenza, and so it also advised WHO to take all steps to facilitate the production and development of a swine influenza vaccine that would be effective in people against this new virus.

At this time, WHO has been working on this and has been working closely with partners to facilitate the development of vaccine candidates that can be used in a human vaccine against this virus and since there are so many partners and different groups involved in the vaccine process, WHO will be facilitating working very closely with all of them to make sure that this process can proceed as quickly as possible.

I think I will stop here and see what kind of questions you may have on any of these topics. Thank you.

**Mr Hartl:** Dr Fukuda, thank you very much and I would like to remind the journalists before we start the questions that there will be an audio file produced after this press briefing and that the Director-General's statement after the Committee meeting will be posted tonight. Tomorrow, there will be a transcript of this virtual press conference and now, to the questions. I know there will be a lot of questions but we will do our best to take as many as we can. Our first question is from Miguel Marquez of ABC

**Miguel Marquez from ABC:** I am curious about the numbers, essentially the number of sick, the number of deaths in Mexico and any light you can shed on the individuals who have died in Mexico and who they are, how old and who they might be.

**Dr Fukuda:** Sure. The picture continues to evolve and so, I don't want to go too much into the details. The Mexican authorities are investigating very hard to get these kinds of details on the cases. You know, what kinds of people have died, what kinds of people have had serious illness and to try to get that picture a little bit clearer. We do know that among the laboratory confirmed cases that seven of these viruses have come from people who have died and in addition we know that, I believe, another twelve viruses came from people who had very serious respiratory illness.

**Helen Branswell:** Dr Fukuda, any explanation of what it would take to make a swine flu vaccine? Can it be done without disrupting the production of the northern hemisphere flu vaccine?

**Dr Fukuda:** I think that there are a number of different options about how the vaccine could be made. For example, it is possible to think of a situation where some companies are working partly on swine flu vaccines while there are also producing seasonal influenza vaccines. I suppose that it is also possible to imagine a situation where some companies are working on a swine flu vaccine and other companies are working on a seasonal influenza vaccine. However, at this time, I think that we still don't have to make the decision about whether to stop seasonal vaccine. We do, however, have to move ahead as quickly as possible to work on making a swine flu vaccine so that if we decide that we need to go into production and stop seasonal influenza vaccine, that this could be done as quickly as possible. I think also though if it is felt that if companies should go into production with the swine influenza vaccine, it is likely that this would reflect an assessment that we have moved even closer to a pandemic and at that time the main objective would be to make as much pandemic influenza vaccine produced and available and accessible to all countries in the world as possible.

**Emma from ABC Australia:** I'd like to know how quickly a vaccine for this virus might be available.

**Dr Fukuda:** I think that it is a little bit difficult to give you a precise figure but in general it is felt that it would take about 4–6 months to develop a vaccine and to begin to have the first batches of the vaccines available. It then will take several more months to produce an appreciable and large quantity of the vaccine. One the things I do want to point out however is that in the past few years the situation for vaccine production has really changed considerably, and that vaccine production capacity has increased considerably, partly because there is more manufacturing capacity and partly because the technology itself has changed. Based on the work done with avian influenza viruses, there are now vaccines that use adjuvant which allows to use much less virus to get a strong immunology effect. And so, the situation itself, in terms of vaccine production, is a little bit fluid, but in general it will take probably 4–6 months for the development of such a vaccine.

**Gareth, from Mexico City:** The numbers of reported deaths here in Mexico are rising around 20 to 50 a day from most reports, and my question is: what is the standard pattern of increase in these deaths, if there is such a thing in cases of this type of virus according to WHO projections and prior research?

**Dr Fukuda:** Clearly there is no standard picture for how these things develop and this is a new influenza virus, so we really don't know how this one will evolve and how the disease related to this one will evolve. So I think that I do want to point out, however, that right now the most solid information and the most solid analysis we can do are based on the laboratory-confirmed cases of influenza. Right now, many of the cases that are being reported both the disease cases and deaths, really are clinical cases of illness and we still don't quite understand in Mexico what is the relationship of this new virus to these new disease cases. Again there is no standard picture for how this will develop; you can already see from the situation in other countries that some of the cases can be very mild whereas it does appear that in Mexico we do have more severe cases and we are working very hard to try and understand why.

**Martin from Science Magazine:** I would like to know what exactly convinced you that a travel ban or travel restrictions or closing the borders won't be effective in delaying the pandemic. There was a study a few years ago by researchers from Harvard who showed that you might be able to win several months that way by closing the borders or grounding all the planes; and also WHO's pandemic preparedness plan seems to say that one of the objectives of Phase 4 is " to contain the spread of human infection within certain limited foci, so has that objective been abandoned now?

**Dr Fukuda:** In the current situation we now see that the virus is quite widespread in a number of different locations and what this suggests, is that at this time instituting travel bans would really not be very effective in preventing further spread of this virus. There has been a great deal of modelling work and a great deal of work done by a number of different epidemiological and modelling groups to look at the situation and by and large, you would have to institute very very draconian restrictions on travel in order to have an impact on the movement of this virus; and so, at this time, it is felt that what is the most important priority as it always is, is the protection of people, and so the focus of the effort really should shift over towards the mitigation and the protection of people.

**Jonathan Lin from Reuters:** Could you explain why you didn't raise the level straight to phase 5 given that the disease is now appearing in more than one WHO Region; and secondly, could you say when you published the revised guidelines on the pandemic alert guidance as it appears on your web site? It seems to be there today but not a few days ago.

**Dr Fukuda:** In terms of the consideration of phase 4 vs. phase 5, the Committee discussed the epidemiologic situation very carefully, and based on that evaluation and the overall assessment of both laboratory cases, but also looking at the cases of disease of which were not a 100 percent certain of how they relate to this virus, it was clearly felt that we were seeing human-to-human transmission and that put us in to phase 4. However, there is a recognition that we really would like to have more information on the sustainability of this virus and one of the examples of sustained transmission for example would be widespread community outbreaks. For example, if we look at the case that was reported in the news in Spain late today, you can see that this case of an infection of a traveller returning from Mexico and we don't really have any evidence of community spread or of infections occurring within a country, which is really what we are looking for in terms of geographical spread.

Now, in terms of the guidelines themselves, the guidelines have been under development for about the last year and a half or so, and the process has involved several hundreds of scientists and public health officials from a very large number of countries and so this has been under development for over a year and a half and so they have been going through clearance – very slow clearance for the past couples of months – and they recently got published and so they got posted on the web site very recently; I think yesterday.

**Daniel from TV Global Brazil:** I have a question about vaccination. I am a little confused here. Have we decided to at least start developing the vaccine in a small lab, I'm not talking about starting a widespread production of the vaccine.  But the follow up question is what would it take to then go to the production stage in which you mention it would take 4-6 months to get it out to people, would it take raising it to level 5 or what exactly are we looking for the next Phase to start working on this vaccine?

**Dr Fukuda:** The production of influenza vaccine take several different steps and in the production of influenza vaccines, we normally have several different groups involved in the process. One of the first step is the development and identification of appropriate viruses to go on to a vaccine and the processing of those viruses, and in turning them into candidate viruses, and then getting them out to different companies so they can test and see how well they grow, how well they process. Typically, when influenza vaccine is developed, it really involves a large number of companies as well as a number of laboratories in the public health world to identify the right viruses, and then typically it goes out to all companies who produce vaccines. This is probably the process that would be followed for making a swine flu vaccine, although we would do it in an expedited fashion as possible because there are also several different regulatory and safety considerations which are gone through, really very many steps for again we would expedite this as quickly as possible. Then as discussed earlier, once we begin this process. If we move it along quickly we hope to have a vaccine first begin to appear in about 4–6 months and then, once the initial vaccine appears, it would then take several months to begin producing lots of vaccines. That in general is the process.

**Maria Cheng, from AP in London:** I was wondering if you could comment on how likely it would be that we would move higher on the pandemic alert level if we might go to 5 or 6 on the pandemic level? Is there a timeline for the experts to meet again and then, if you could briefly comment on the pattern in transmission and if you have any idea on how long the transmission chains are and how sustained they are?

**Dr Fukuda:** I think that it is fair to say that a move from phase 3 to phase 4 signify that we have taken a significant step closer, but as I mentioned earlier we are not there yet and that the situation could change. I think it is also fair to say that for the past few days we have seen how quickly the situation is evolving with new cases being reported. It is possible that we could stay in phase 4 for quite a long time, it is possible that as the situation evolves over the next few days, it could evolve to the point where that it appears that we have moved into phase 5, and it is also possible that the disease situation could be quieter and we could move backwards to phase 3. I think at this time, again, the situation is very fluid and it is possible that we could move to a higher phase in a relatively short period of time but it also possible that we could stay at phase 4 for a quite a while as the situation perhaps stabilizes. I think that right now it is a little bit difficult to give you a likelihood but it does reflect the fluidity of the situation.

Now, in terms of your second question, one of the ways that we look at transmission sustainability, is to see if we have large outbreaks and then try to figure out what is the incubation period of this virus, for example, how long does it take between the time a person get infected and develop symptoms, or develop disease, to how many people does an infected person pass on viruses and those kind of factors, and that is often how we analyse outbreaks and that gives a good picture of whether we think there are many generations of spread. When we see that a virus is able to move from person to person, and continue that in a way that we see in community outbreaks or large, institutional outbreaks then we generally feel that we have sustainable person-to-person transmission. Right now, again, we have a minimum amount of data on some of the factors such as the incubation period and we are really working very hard to document how many generations of transmission are available. Again this is much of the work being done by investigators in various countries to document that, so I think that this pretty much sums up where we are right now in terms of that detailed information.

**Andrew Jack of the Financial Times:** Could you clarify when WHO was first notified of suspected virus from Mexico because I have seen some reports coming back some weeks and secondly, there is some debate arguing about whether it is a misnomer to call this swine flu, because there seems to be avian elements as indeed sometimes there are porcine elements in avian flu so is it a misplaced definition which actually could cause unnecessary confusion.

**Dr Fukuda:** I will answer the second question first; this is similar to a question that came up yesterday. When the viruses that have been isolated from people who have developed this illness are looked at, it is clear that these are viruses that have genes and have a virus structure which indicates that they are a swine influenza virus. That is they are an animal influenza virus generally adapted to circulate in swine. Now, this influenza virus contains many different genes and there is a mixture of genes in these viruses, but by and large, when you analyse this virus it is a swine influenza virus.

However, it is somewhat confusing because it is a swine H1N1 virus and there are other different swine H1N1 viruses that are different from this one, and there are also H1N1 that circulate in people, that is they are human H1N1 viruses. I appreciate the difficulty of keeping all this straight but these are a new swine influenza virus: they are new for pigs and new for people. In terms of your question about the exact date, I think this is something that I would have to get back to you again about when we were first notified about illness activity in Mexico, but I believe that the first indications that we had about this virus was the report of the first two cases from southern California which came from the United States, and before that we were not notified about swine H1N1 viruses in Mexico. Mexican authorities themselves have been looking at illness cases in Mexico and beginning their own investigations but I believe that at that time they were not known as being swine H1N1 influenza viruses, but we'll check on that and get back to you.

**Jemil from Sao Paulo in the Press Centre here in WHO:** I have a question regarding Phases 4 and 5: did you take any consideration regarding economical and political impact in this decision or was it purely a technical one; secondly from our Mexican colleagues, they are asking whether Mexico has enough stocks of Tamiflu® or any other medicines in order to not contain as you said, but to mitigate the problem; and thirdly is Latin America specifically at a higher risk or is it at the same level as any other region in the world?

**Dr Fukuda:** I think that it is fair to characterize the deliberations on the Phase change about Phase 4 vs. Phase 5 in this way: the considerations and the discussions focused purely on the technical issues; that is: what is the epidemiological pattern, what can we say about the spread, what can we infer about the transmission, what is the difference between community spread versus having travel-related infections and so on, and using those discussions to decide what was the appropriate Phase at this time. However, it is also fair to say that the Committee was very aware that going to a Phase change really has quite significant political and potentially economic implications for all countries. The Committee was mindful on the fact that once this kind of Phase change is made, that it will have profound potential implications for everybody.

So, the Director-General did listen to all of these considerations but the main focus and most of the discussions really focused on what do we know about the epidemiology and what can we infer about it. Regarding the second question on whether Mexico has enough antivirals, the Mexican authorities did indicate earlier in the week that they had approximately over 1 million courses of antiviral drugs available at that time, but they were mindful that it was possible for these supplies to go down lower, depending on how the situation develops and that they could be used up, and so we are working and keeping in close contact with the Mexican authorities about their needs for antiviral drugs. If the situation does escalate however it is clear that other countries in addition to Mexico will also need antiviral drugs. So we are working very closely with the manufacturers about how the availability of these drugs can be made possible.

In terms of the question of whether Latin America is at increased risk, at this time it is clear that the most of the swine H1N1 influenza activity is taking place in North America with much of the activity taking place in Mexico. I think that in this age of global travel, where people move around in airplanes so quickly, there is no region to which this virus could not spread and if we move into a pandemic situation, then by definition that means that all countries around the world would be at risk of pandemic influenza.

**Gregory Hartl:** This has been the second virtual press conference and we will continue from now on the regular virtual press briefings at 15:00 GMT tomorrow and in the days to come. Thank you once again to you all.

## 27 April 2009 - Press Conference at 17.00hrs.
## Gregory Hartl - Spokesperson at WHO

**Gregory Hartl**: Quick update today, swine flu developments and what WHO is doing

We now have 40 reported cases in the USA and 26 in Mexico, there are cases in Canada and we have a verified case in Spain.

We have seen the disease spread geographically, and because of this spread and because of the increasing number of cases, the second meeting of the Emergency Committee which had originally expected to convene tomorrow, has been brought forward to today. That Emergency Committee meeting is meeting at this moment, it started approximately an hour ago and as soon as possible after the end of that meeting, we don't know exactly when it will end, but after the end of that meeting we will let you know in a second meeting such as the one I am holding with you now what the outcome of that meeting was. It will likely be Dr Keiji Fukuda who gives the subsequent update.

I am just here to let you know that today and on subsequent days, at this time, 17.00hrs Geneva time, we will be here for you and if you have any questions now to tide you over until the end of the Emergency Committee meeting, please go ahead.

**Journalist:** The Emergency Committee will obviously be meeting about or deciding about whether to raise the pandemic alert level, is it conceivable that it might go from 3 to 5 today.

**Gregory Hartl**: There are two considerations on the table, we don't know exactly will happen, and we would not want to prejudge or pre-empt the discussions in the Committee. If you look at it, the disease is spread as we know, we have confirmed cases in four countries now plus rumours of cases in other countries, so it is beyond one specific foci which is the normal definition of phase four, but there are other considerations to the effect of the fact that we don't know for example how much human to human transmission in communities in these other locations. It might still be the case that all these cases are imported cases. There will be judgements made because of that as to whether Phase 4 or Phase 5 is more appropriate.

**Journalist:** CDC has been saying since Friday that they do not believe that containment is possible. My sense dealing with WHO since then was that there was a bit of a surprise that the Americans would have said that right out of the box. And WHO has not renounced yet the notion of trying to contain this outbreak. Are these discussions likely to lead to a conclusion on that subject as well.

**Gregory Hartl**: I wouldn't want to pre-empt what they decide, but given the geographic spread of the disease, being able to mount an effective containment effort would probably not be feasible. Again unless it is found that most of the cases emanate from a single area, and that the cases we are seeing in other countries are for the majority imported cases because of travel for example to that original given area.

**Journalist:** you have a GOARN team in Mexico and everyone has been very keen to get a sense of what is actually happening there, what is the epidemiology, the disease, are there a large number of mild cases that just aren't coming to the attention of authorities. Is that picture becoming any clearer, have they been there long enough to help to sort out a bit?

**Gregory Hartl**: They haven't been there long enough to have a complete picture, but certainly that is one of the questions we are looking at. As we have known since the beginning, this event, one of the pieces of the puzzle which is perplexing is the fact that in the US and Canada we are seeing only mild cases whereas in Mexico there have been a few instances of such severe cases that it has caused death. We don't consequently believe we probably have yet a full picture of the breath of illness that this disease is causing. This is obviously one of the things that the GOARN team is looking in to. As I understand it the GOARN team is currently looking at three different locations in Mexico. So hopefully soon we shall have some answers. The Emergency Committee deliberations are confidential and private but certainly what they might be getting today already from the Mexican representatives on that Committee, is feedback into some of these investigations.

**Journalist ABC News:** The deaths in Mexico, there were three that were directly related to this variant of H1N1 virus and I am just curious, there are reports of as many at 103 people dead in Mexico from what they are saying is the 'flu. Are all those still questionably possibly this particular variant? Have some of them been ruled out? Or are they from some other respiratory illness, can you give us a bit more on that.

**Gregory Hartl**: I do not have the first hand knowledge to be able to comment authoritatively on that. I think that there are certainly the case definition that they are using to pick up cases and I think quite rightly in the early stages of a new disease casting the net very widely, so they are looking at influenza like illness, they are looking at acute febrile illness, they are looking at pneumonia events, so consequently there are a lot of thing being picked up. How many of these will actually result in a confirmed cases is very much still up in the air, because as we know at the last count there are 26 lab-confirmed cases in Mexico. That is far, far under the high numbers that have been thrown out.

**Journalist from Associated Press:** You said earlier that the Committee would be discussing whether Phase 4 or 5 was more appropriate. Now does seem to indicate that you will be raising it beyond Phase 3. Did I understand that correctly? Will a phase change definitely happen and it just a question of how high it will be.

**Gregory Hartl**: I can't prejudge the work of the Committee so I would not want to say anything definitely because we don't know the outcome of the Committee, but the fact that we have called the Committee a day early would certainly seem to indicate that we believe that this an event and an evolving situation which needs to be addressed urgently.

**Journalist Reuters:** Could you tell us whether virus samples are now being sent to pharmaceutical companies. Could you also tell us the last time the pandemic threat level was increased? Also could you tell us if someone will be present physically at the UN briefing tomorrow morning?

**Gregory Hartl**: We understand that US CDC for example has already taken wild virus and has produced a vaccine virus strain and is currently growing this strain, the virus in eggs which is the first stage in a vaccine production process, and we have seen the media reports like you that some vaccine manufacturing companies are already preparing to produce a vaccine against this strain H1N1 so we certainly know that the work has begun to produce a vaccine. Remember that a vaccine because of current production, the current methods, it takes quite a while to happen. Basically you have to grow virus in eggs first. So from start to finish of producing a vaccine, a virus vaccine, until getting a vaccine on the shelves for use by people is probably five to six months.

Fadela Chaib or I will be at the Palais tomorrow.

The current pandemic phases were first introduced in 2005 when we revised our pandemic guidance at the beginning of the avian influenza alert. It was at that stage, pandemic Phase 3, because as we have seen with avian influenza still it is a virus which is very predominately in birds in various types and very occasionally jumps to human beings. So that is Phase 3 and we have never been at any phase higher than Phase 3 under the current system of pandemic phases.

**Journalist, Time Magazine:** Does the WHO have any comment on the EU Health Commissioner urging Europeans to avoid travelling to the US or Mexico if it is not essential. This virus seems to be passing across borders, passing across countries, and we have CDC saying that containment doesn't seem to be possible at this point. Is there any value to those kind of warnings?

**Gregory Hartl**: Certainly WHO does not recommend any travel restrictions and we need to be very clear on that.

**Journalist Washington Post:** You did say there are now 40 confirmed cases in US? Have there been any deaths? Did you have any new numbers on top of this?

**Gregory Hartl**: 40 confirmed cases in the US as I remember, 26 in Mexico and 6 in Canada and 1 in Spain. These are the latest numbers I have. Certainly the cases in the US, Canada and Spain have all been mild cases. There was one brief hospitalization in the US in the earlier set of cases, in Texas, in California, but that person soon left hospital and is well on the way to recovery now. The only severe cases we have seen are in Mexico and that certainly again is a big part of the puzzle, why we have teams, Global Outbreak Alert and Response network going currently has teams on the ground trying to understand better the patterns of infection and the source of infection. And even if there might be co-infection and why certain groups of people have been so susceptible to this virus in Mexico, much more so, or much more badly affected by this virus in Mexico that in other places.

**Journalist:** In terms of the pandemic alert level, could you talk about what happens as a result of raising it to Level 4 or Level 5. Are there any specific actions that will follow from that.

**Gregory Hartl**: In pandemic alert level 4 - 4 is basically when human to human transmission, or sustained human to human transmission is limited to one relatively contained geographic area and it is felt that there is a possibility of a containment effort being successful, i.e. that we would send it very large teams to ring fences or seal off that area, or blanket that area with antivirals, and also maybe vaccine to people who have not been infected yet if we had the vaccine, but obviously we don't have a vaccine for a novel strain. In order to try to reduce the viral load in the majority of the people in that area and then consequently reduce slowdown and very extreme situations even stop the spread of this virus. So that is pandemic level 4, and basically as you can understand it is more of a very punctual concentrated local effort. And that is normally undertaken when there is only sustained human to human transmission in one given area.

So the question is in pandemic level 5, that would mean that we are seeing various foci of community transmission over several generations in geographically different places. If we make the determination, or if the determination is made now or in the coming days that there is sustained community level transmission, then that means that the virus is much more widespread and in that case there would be decisions needed to be made on switching over vaccine production from seasonal vaccine to a pandemic vaccine. There would be other decisions needed on stocks of antivirals, on what to do with antivirals, on health system provision because you can expect that if there are large, large numbers of cases then maybe health systems will be over run so you would have to start triaging cases and ensuring that you deal with different types of cases differently.

Pandemic Phase 6 which the highest phase basically means that it is spread across continents.

**Journalist:** Given the description that you have just put out, it would seem that we have spread across continents, although there hasn't been community level transmission. Would it not have been expedient for the WHO to have perhaps stepped up some of its warnings or some of its actions given what we have now.

**Gregory Hartl**: I am not sure what WHO could have done that it hasn't already done. I think the extent of this event only became clear to the world in the course of the past week and already on the night from Thursday (23 April) to Friday (24 April) we went into an emergency 24 hour operations mode here at WHO and on Friday began to launch the mechanism which resulted in the calling of the first Emergency Committee meeting on Saturday. We have done everything we can especially as we said yesterday, the day before, in the course of the past week, there are still a lot of questions which need to be answered about the transmission of the virus in Mexico. We all know that the biggest reported or suspected number of cases are from that country, but we still know that there are only 26 confirmed cases now. So out of the thousands or so cases which people have been banding about in public fora, really the number of cases we are sure of is much much smaller. So before we change phases it would have been irresponsible of us not to understand the nature of the outbreak better before we changed phases. When the Emergency Committee first met on Saturday, that was one of the big conclusions out of that meeting, certainly this looked like an event which could develop into something much bigger and as Dr Chan said, this was a virus that had pandemic potential and because it had pandemic potential, we are looking at a rapidly evolving situation. Expert Committee agreed that this should be classified as an international health emergency, but still the Expert Committee also agreed that we need more epidemiological information and that is why we did change phases then, we shall see what happens today.

**Journalist, German Press Agency:** When do expect that the meeting will conclude and when will you be able to brief us on that? Are you seeing any new strains or new DNA emerging from this 'flu and will the UN, as I see with Dr Nabarro, be participating in the efforts to constrain the spread of the disease?

**Gregory Hartl**: what we understand is that a great number of these viruses from the various locations are genetically quite similar if not identical. WHO is the United Nations system lead on health as our name would imply and the response to this event, the technical expertise from this event all comes from WHO, but certainly this event, especially if it evolves into a pandemic, is an event which is going to necessitate that we all work together as much as possible and certainly Dr Chan has already been liaising on a regular basis with all our UN partners.

**Gregory Hartl**: The Emergency Committee is meeting now. It is not guaranteed that a decision on phase change will be taken. This is one reason also why I wanted to meet you now to keep the 17.00hrs time slot active because we might have to come back later and say "no decision tonight, maybe again tomorrow or in the coming days". But there is a good likelihood that something will happen without prejudging the committee. The previous meeting on Saturday lasted two hours with then the notifications of our various national focal points and we were able to go public with that at about 8 or 9 o'clock, so I would expect that that would be the same time frame we are looking at tonight. We cannot give you an exact time for the follow-on virtual press conference this evening and we shall keep you informed.  The email alerts when we know anything with any more precision.

World Health Organization

# Transcript of Virtual Press conference with
# Dr Keiji Fukuda, Assistant Director-General ad. Interim
# for Health Security and Environment
# World Health Organization
# 28 April 2009

Good afternoon everybody. I think we started almost on time today so we are getting a little bit closer. What I would like to do is again provide a brief update of the current situation, go over a little bit of the new developments and then go over some of the main points that we should be thinking about at this time. In terms of the current situation, we continue to remain in Phase 4 and I think that you remember that we recently went from Phase 3 to Phase 4, which was a significant change but we continue to be in Phase 4 and have not escalated that at this time.

Since yesterday there has continued to be an increase in laboratory-confirmed cases of the swine influenza infections. Yesterday we reported that there were 73 infections and today we are reporting that there are 79 laboratory-confirmed infections, as of the information that we had this morning. Again we are mindful that the situation continues to evolve and there are new cases being identified but, as of the information provided to us this morning, we have 79 laboratory-confirmed infections. These are reported from the United States with 40 laboratory-confirmed cases (these come from five states); we have 26 laboratory-confirmed cases being reported from Mexico (these come from four different states); in Canada we have 6 cases reported (these come from two provinces) and then we have 2 cases being reported from Spain, 2 cases from the United Kingdom, and 3 cases reported from New Zealand. There have been 7 deaths among these total number of cases, and all of these have been reported in Mexico.

In terms of new developments, it is clear that the epidemiological situation continues to evolve and we continue to press ahead with investigations to understand the situation. In terms of the movement of this virus, we see that there have been two new countries that are reporting infections and these are the United Kingdom and New Zealand. I want to make some important points related to these latter cases because I think it will help everybody to understand the Phases and how we are assessing the overall situation. The recent cases that have been reported from both the United Kingdom and New Zealand are infections in travellers returning from overseas: these are direct travel-related infections. They are really critical to identify. Right now it is critical to identify every case because it helps us to monitor what the potential spread of the infection is worldwide and how the epidemic is moving. It is also important to identify these cases because these are infections in people and the sooner these infections can be identified, the quicker people can get the optimal treatment that they need in this situation.

But in terms of assessing the epidemiological situation and in terms of considering when there should be a Phase change, what we are also looking for are cases in outbreaks indicating that the infection is becoming established in a community, or becoming established in a country. Even though we know that the virus has reached at the United Kingdom and New Zealand for example in the form of infections in travellers, this is still a different situation than the infection becoming established in a community in those countries; this is a distinction that is important epidemiologically and important for everybody to understand.

In this situation, WHO continues to work very closely with all governments but especially with those governments in which the infections are occurring. In addition, WHO is continuing to work very closely with Mexico in the form of providing assistance for these investigations.

One of the ways that WHO does provide assistance to countries is to provide expert staff, for example laboratorians or epidemiologists and so on, and we often do this through something called the GOARN Network (Global Outbreak Alert and Response Network), which is a way for international institutions – public health institutions – from around the world to work together to bring the resources and consolidate the resources together and really to provide help where it is needed. It is one of the useful ways in which the international community really gets its act together and really provides help where it is needed, when it is needed. In addition WHO continues to work with many partners around the world to consolidate our understanding. So, the work on surveillance, the work on research in the viruses, on understanding the epidemiology, this is really done by many different people in institutions around the world, and WHO helps to facilitate this and to coordinate this. Some of the organizations formally associated with WHO also continue to do a very critical work.

The WHO Collaborating Centres – and these are reference laboratories in the United States and in London, UK for example – are working on the development of vaccine virus candidates and these are the vaccine viruses that are going to be needed to make a vaccine. In addition, there are other laboratories which are also working on these kinds of vaccine candidates and this is the kind of work that we are pushing ahead very hard on, so that we can have a vaccine as soon as possible if it is indicated. In addition, the WHO laboratories continue to work on the development of diagnostics and reagents which will be needed by laboratories around the world to diagnose these infections if they reach other shores.

In addition again, as I mentioned before, WHO continues to provide as much guidelines and guidance to countries as possible and so we have guidelines up there for clinical diagnosis, we have guidelines up there about surveillance, about case definitions, about how to conduct some of the laboratory work for these infections. In this way we are trying to work with our partners, we are trying to provide as much assistance as possible so that we can monitor and deal with this situation.

In assessing where we are right now, yesterday's move to go from Phase 3 to Phase 4 was clearly an important step in alerting the world, really sending a signal that we are dealing with a very serious situation, but as I also mentioned yesterday, we are not positive about how this situation is going to evolve and the evolution into a pandemic at this point cannot really be considered inevitable, but of course we are taking this possibility extremely seriously. I think the point here is that we really are in a period in which countries should take this opportunity to prepare themselves for the possibility of a pandemic, especially for the countries which are not yet dealing with an established infection in their country. This is really an important time to look at your plans and to prepare as much as possible. Now, we are continuing to deal with the immediate situation, the urgent situation, the spread of the virus in a number of different countries, but we are also looking ahead to the possibility that we could go into a pandemic situation.

One of the important tasks at this point is to anticipate the needs of countries if we go into that situation. In particular, what we are really focusing on, or beginning to focus on, is the anticipated needs of developing countries if the pandemic should develop and if those countries get impacted. We know from history, we know from the analysis of past pandemics, and we also know from many infectious diseases and health problems that the poorer and the developing countries are the ones who really get hit the hardest. They are really hit disproportionately hard and they also have the least resources to deal with these kinds of situations, and so we are mindful of that and we really would like the help of countries and organizations to also help anticipate and to meet those demands. This is a very important role for the international community.

Now, the last point I want to make is that in this situation, WHO is very focused on this emergency situation. We are putting all resources possible into dealing with the current situation, but we are also mindful that even in this kind of situation, other urgent health matters and issues do not go away. There are still many other health problems to take care of, there are still many other diseases that have to have attention and so, while we deal with this situation, it is important for WHO, but it is important for other health agencies in countries out there to be mindful of these other health priorities that continue to need attention.

I think that I will stop at this point and see what questions we have today.

Thank you.

**German press agency in Geneva:** I just wanted to clarify something regarding the names. I have seen that the ECDC (European Centre for Disease Control) is now renaming, saying that they prefer to rename this nouvel influenza. Does WHO have an opinion on the name as I can imagine the importance to have a single name that everyone uses in such a situation: if you could clarify the status of the name? The second question is regarding the discrepancies in numbers; we see some countries are reporting numbers that WHO has not right now; you said 79 cases, but if you count the numbers from the countries it is a bit higher. Can you just explain how WHO is counting the cases?

**Dr Fukuda:** Let me take the second question first and then come back to the first question. There are a lot of numbers floating out there and in the first interview we talked about the possibility of a lot of confusion over numbers in part because in some instances we are talking about laboratory-confirmed cases, in some instances we are talking about disease cases, which have not been confirmed specifically due to this new virus. And then also the world is a 24/7 world now and so numbers come in from different countries around the world at different times. In this situation as the epidemiological situation itself changes and as the world is awake at one part of the day, and then the world is awake in another part of the day, and if we have different kinds of cases, the specific numbers can be a little bit hard to keep track of, and certainly we see different numbers reported at different times.

What WHO reports right now is we are really focusing on the laboratory-confirmed cases. These are the ones that we specifically know are due to this virus infection, and the numbers that we report are the numbers that are being reported officially to us by the country I think at times during the day there can be different numbers reported by media sources and so on, but we are reporting numbers that are reported and verified by the countries in which they are occurring. Now in terms of the name, again I think that the naming of new diseases, the naming of epidemics can be very confusing. At WHO we have not initiated any plans to try to change the name “swine influenza”. This epidemic started basically with that name and the virus that is identified is a swine influenza virus, and we are hopeful that the introduction of new names does not cause any undue confusion. But right now we do not have any plans to try to introduce any new names for this disease.

**National Public Radio USA:** If travel to Mexico diminishes, presumably it is and it will, and as travellers start returning home with the virus from wherever they came from in the next week or so, if there are no more cases that are appearing elsewhere, will that tell us that the trends of transmissions are short, and that the likelihood of sustained-community transmission is less or diminishingly small? And second question is: how long do you think it is realistic to expect, I realize that you cannot be precise about it, but before WHO and others get the data from Mexico that can be used to plug in to the models that are already there to make a first step at calculating things like peaks of virulence or cases.

**Dr Fukuda:** In terms of the first question that involves a little bit of speculation but if travel decreases to the effected countries and we see fewer outbreaks occurring and fewer infections occurring, we will know that in fact the situation is over. One of the things about influenza is that we see big peaks of influenza during the winter months in both the northern and the southern hemispheres, and then in the tropics we often see peaks of activities occurring a little bit less regularly. And then during those non-peak periods it often appears very quiet. So I think that when we see the introduction of a new virus like this, which clearly is able to transmit among people, I think it will be very hard for us to know whether this, even if activity goes down and becomes quiet over the next few weeks, very hard to know whether this virus is actually disappeared until several months have gone by at the very least. That is the nature of this infection and that is something that we would be on the look out for. And here again, I think that we can look to avian influenza and if you look at that virus you will see how it seemed to have disappeared for periods and then reappeared with a vengeance. And so it is very hard to know when something like this disappears. I do not think that we will be able to conclude that in the next few weeks no matter what happens.

In terms of the second question, how long before we know about specific characteristics of the epidemic such as the I nought which is really a number which describes how likely or how often does an infected person pass infection onto other people who are uninfected. Some of this information may come from Mexico, some of this information may come from the outbreaks or cases occurring in other countries. We hope to have this information of course as quickly as possible, it would really be nice to have it within the next few days or so, but at this point I cannot second guess the investigators out there and it may still be several days or longer before we have that kind of information or even longer than that.

**Reuters in Geneva:** First question, from what you seen so far with the patterns and the changes with transmission, particularly in the US, have you seen any trends there that could lead to an increase in the pandemic level when the Emergency Committee next meet? But also, I wondered if you had any detailed information about what is causing the fatalities that occurred in Mexico and what about the flu there proved deadly?

**Dr Fukuda:** The move from Phase 3 to Phase 4 reflected that after assessment we think that the virus shows the ability to transmit from person-to-person, so this was an important step. If we go from Phase 4 to Phase 5, what it really tells us is that the virus is becoming established with sustained human-to-human transmission in a number of different countries. So at this point, we will continue to monitor the situation and it is really based on that monitoring: what we see going on in the countries, now but also when we see what happens in other countries, whether the infection becomes established and leads to human-to-human transmission on a sustained basis in those countries. So this is really a monitoring situation. In terms of the fatalities in Mexico, we still do not have a good explanation for why the pattern of cases in other countries appear relatively mild and why the pattern of cases in Mexico appear to be much more severe with the deaths and the severe pneumonia cases. This will be the object of a great deal of research and attention but at this time we cannot say why there appears to be a difference.

**The Washington Post:** When issuing a travel advisory advising residents not to travel to certain places specifically Mexico, do you think it is a good idea? And the second question, can you can elaborate just a little bit more on the question about the difference in severity of the disease in Mexico and elsewhere and what kinds of things you will be doing to try to investigate the explanation for that?

**Dr Fukuda:** This is a good question. In terms of the travel advisory, yesterday I spoke a little bit about WHO's recommendations on travel. Just to remind people, one of the decision of the Director-General of WHO is that we do not recommend border closures and we do not recommend restrictions of travel; we do not call for any restricted travel to any country. However, we are very focused on the safety of the people who may be infected with this new virus or with any other important infection and so, with regards to that point, WHO does strongly recommend that people who are sick should strongly consider deferring travel, that is stay home until you are feeling better and also for travelers who have travelled somewhere and return feeling ill, that they should seek a proper medical attention to see whether this is possibly something that can be treated or in the case of swine flu something that also has to be diagnosed and reported. Now, we are also very mindful that the considerations of different countries have to take a lot of different factors into consideration, and in doing so, countries can come up with their own conclusions and in this kind of situation some countries make a decision to issue one kind of travel advisory or another.

WHO recognizes that countries see these things differently and make different decision and we do not have any issue with this at all. From the international perspective when we look at whether travel advisories may slow the spread of infection, may slow the spread of the epidemic, we believe that at this time, these kinds of manoeuvres would not substantially help to do this, and so we are strongly emphasizing a focus on the safety of travelers and that is why we are recommending that people who are feeling ill defer travel as possible and people who become ill to seek proper medical attention. In terms of trying to figure out the severity of the illness there are a number of different things that are useful to do. One of them is to understand the overall pattern of infections and disease by looking at the epidemiology. For example, to look at all of the people who have gotten infected to see what ages they are, to see whether deaths and serious illnesses appeared to be close to one group of people or another or different age groups. This is one kind of basic analysis.

Another kind of study is to look at the clinical cases themselves and to see if there is anything in the background of these people which suggests why they may have had a more severe outcome than other people. And then there are other kind of studies which are laboratory studies, either immunological studies to see whether there may be antibodies which help protect the people who got better, or who stayed less sick, is there any other reasons why the people who develop severe illness got sick based on laboratory tests. Then finally, you do things such as looking at the virus: is there anything different between the virus infecting the seriously ill people versus the mildly ill people. In terms of the latter our information suggest now that we have seen no difference in the viruses infecting sick people and less sick people. It is likely that that is not the answer.

**Globe and Mail in Canada:** Can you talk a little bit about the origin of the virus; there are reports that the origin are in La Gloria in Veracruz state I wonder if you could talk where you think it originated this swine flu?

**Dr Fukuda:** I know that there is a fair amount of speculations about where the virus may have originated. I think that right now it is not possible to really know where this virus originated. Most of the virus that we see out there are very similar to each other suggesting that they were a newly emerged virus rather than one that has been around for a while, and has many different variants, but I think it is too early right now to speculate about the origins.

**AP in Geneva:** My first question is WHO said it is investigating possible human-to-human transmission in the case of the New York school and officials have just said nine people came in contact with the confirmed cases, is it inevitable the virus would take hold outside of Mexico?

**Dr Fukuda:** I think it is probably too strong a word to say that it is inevitable. I know that in New York City some of the students who had become ill did not travel, again suggesting that the virus is able to have person-to-person transmission, from travellers to people who did not travel. It is also as far as I understand true that these infections took place within a school setting and so with influenza we often see that people who are in institutions, these may be day cares, they may be nursing homes, they may be schools, are often sites where outbreaks occur, which is still a little bit different than outbreaks occurring in large institutions or large communities which would be towns, villages or cities, and so there is definitely the possibility that the virus can establish that kind of community-wide outbreak capacity in multiple countries. This is something we are looking for very closely but I think it is too early to say that it is inevitable. It is definitely possible, it is very serious possibility but it is still too early to say that this is inevitable.

**Fox News:** These are different diseases what has the WHO and international health policy experts learnt from the 2003 outbreak of SARS or avian influenza that can be used today to combat swine influenza at this point. I saw on the WHO website that you guys are working towards mitigation measures instead of containment, but I guess SARS was also kind of geographically diverse I realize these are different viruses and have different transmission abilities but if you have any parallels or can draw out any guidance from that?

**Dr Fukuda**: It is a very important question. I think that the first lesson that was learned and this is a lesson that these new diseases teaches over and over again, and this is equally applicable to an infectious diseases such as HIV/AIDS phenomenon, which why the world continues to be threaten by these new emerging infections. This in not something of the past, this an ever present reality for the world. Ever since from SARS, the introduction of AIDS in that time period up till now, there will be any number of a new important emerging infectious disease of which SARS and avian influenza have been some of the most important and certainly some of the most recent.

What the SARS and avian influenza epidemics both showed is that when this new kind of threat can appear, they can threaten large numbers of countries in many different ways, not just the disease, but the fear these diseases can have effects on economies, on societies, and they can be very wide spread and you look at why this is true you see that the world is really interconnected at many different levels and the world is connected by families being on different continents, by business, by travel and many different things, and so these new emerging infectious disease threats are truly international and global scope. But the same things which make these diseases a threat, that is the ability to move around the world so quickly, the movement of people and so on, are also things which allow us to control them. With the SARS epidemic, we saw that when the world was able to put up resources together, to work together in a coordinated effort, it was really able to contain an outbreak which could have spun out of control. That is probably the most important lessons learnt from SARS.

One of the most important lessons learned from avian influenza is that when you are faced by a threat like this, a lot of the preparations which go into handling that kind of threat have broad applications to many other situations. In this sense, we are dealing with a different virus, however all of the preparation that went into preparing for a potential avian influenza pandemic and to deal with the threat of avian influenza infection for people are really what we are using now to deal with this threat. So the relationships that were built up planning to develop technologies, the work to advance vaccines and so on, all of those are directly relevant to dealing with this immediate threat. I think the big overall lesson is that we are wise enough to take the lessons from these emerging disease threats if we are able to strengthen our planning, if we put our resources into public health planning and infrastructure, we are really much much better able to deal with this new threat. What you have seen right now, even though we are continuing to watch this epidemic evolve and we are not quite sure where it goes. I think that the response by many institutions around the world, by many countries shows that they have learned the lessons of SARS and of avian influenza, that they are applying those lessons and we are much better off for it.

**Daily Telegraph in London:** We have heard from at the ECDC that we might be facing what they described as a mild pandemic because there have been no deaths outside Mexico, and the cases we have seen elsewhere in the world are somewhat milder even than seasonal flu: if you could say something about that concept of a mild pandemic. Can you describe what the WHO representatives on the ground in Mexico are doing right now in trying to confirm more of these cases of H1N1?

**Dr Fukuda:** One of the lessons that history has shown us is that pandemic span from being moderately mild to being extremely severe. My own sense right now is that it is probably too early to make a pronouncement about what kind of pandemic we may see. It is entirely possible as the ECDC has commented we might see a very mild pandemic, and that would be the best of all possible situations short of this current situation simply stopping and disappearing, but I do want to provide a cautionary note. The worst pandemic of the 20th century occurred close to the beginning of that century and it also started out as a relatively mild pandemic, with illness that was not very much noticed in much cases and then became a very severe pandemic and one of the most severe infectious diseases the world has recorded. So I think that we have to be very mindful and very respectful of the facts that influenza tends to move in ways that we cannot predict very easily. I think that at this point the most important thing we can do now, as it will be later, is to maintain a very high state of monitoring and watchfulness and so, this is really much of the emphasis of the new International Health Regulations and this is really much of the emphasis on how we deal on these infections diseases in the 21st century which is really to use every means possible to keep on top of this threat, monitor because we know that they can change very quickly, so this is what we are doing.

In terms of what the WHO representatives are doing, they are doing closely with colleagues of the Mexican Ministry of Health working on epidemiological investigations, trying to understand the data which have been collected to date, trying to work with authorities on collection of new date, trying to make sure that data is collected and tested in a way shed new light on what is going on. In addition, there are people helping with logistics, helping with communications, so there is a variety of different ways in which the WHO are working with the Mexican colleagues so the partnership is working very well right now and I am hopeful that we have a much better understanding of the situation in Mexico in near future.

# Transcript of Virtual Press conference with Dr Keiji Fukuda, Assistant Director-General ad. Interim for Health Security and Environment
## World Health Organization
## 29 April 2009

**Dr Fukuda:** Good afternoon everybody and again thank you for joining this press briefing. We apologize for any technical difficulties. I want to start off with the situation update and provide where we are in terms of the cases of laboratory-confirmed infections which have been reported to WHO. I do not want to put too much of an emphasis on these numbers because we know that the numbers are changing all the time and there are numbers being reported by various media outlets, as well as by countries, but these are the numbers that have been reported to WHO as of 5 p.m. today.

From Canada we have 13 cases from 4 states. Seven of these represent new infections from the last time that we spoke. In the United States we have 64 cases, which is the same number as before, but we do have 1 death being reported now in a young child. In Mexico there are 26 cases with 7 deaths, this is the same as before. In Israel we have 2 cases reported. In Spain 4 cases. In the United Kingdom we have a report of 2 cases and in New Zealand there is report of 3 cases. This is for a total of 114 cases as of 5 p.m. today, which has been officially reported to WHO.

In addition to the officially reported cases, we know that there are a number of other suspicious cases and other infections being investigated at this time in a number of other countries. One of the things that I wanted to touch base upon today is, as part of the overall attempt to handle where we are and what the situation is. WHO this afternoon convened a large global virtual science meeting, which was held by telephone with several hundreds of participants involved from around the world, as well as presenters from some of the countries with confirmed cases. In fact, I believe that conference call is still going on but I will be able to report some of the findings even though that meeting continues.

In terms of the information that has become available through the discussions on this telephone conference, we have a little bit of information now on the clinical spectrum of illness. Based on what the investigators have reported, it is clear that we continue to see severe cases occurring in Mexico. However, in the other countries, the cases continue to be predominantly mild cases, otherwise I mentioned earlier, we do have the report of the death in the United States in a young child. The epidemiological information to date, strongly, more strongly suggests that we are dealing with a virus that is being transmitted from person to person. And the disease transmission through travels is accounting for the spread of this virus in a number of different countries. Studies are under way in a number of countries to look further up the transmissibility of this virus. For example, there are studies under way to look at the contacts of people who are known to be infected. And again, I expect the information to unfold over the days and weeks as we go into this.

Some virology confirmation was discussed today and the most important point is that the virology analysis today again confirms that this was originally a new swine influenza virus, but it is now behaving more or less like a human influenza virus, the transmission going from person to person. At this point we do not see any evidence that people are getting infected from pigs. We do not have any evidence to suggest that pork meat and those sorts of products pose a risk to people. This appears to be a virus that is moving from person to person.

Many countries have increased their surveillance, so they are looking for cases both in general communities and in hospitals. This, as you remember, was one of the actions recommended by WHO a few days ago. Finally, the work on developing vaccine, seed viruses and candidate viruses continues in a number of laboratories, with both laboratories in the United States and Canada working on the development of viruses that could be used in a vaccine.

I think that if we take an assessment of the situation right now and ask ourselves where are we, what is going on and where might we be going, it is clear that the virus is spreading and we do not see any evidence of this slowing down at this point. All of the information that we have both from the formal analysis that are being done, but also from the reports of the investigators on the ground, what they feel that they are seeing, suggests and indicates that we are seeing person-to-person transmission and this is continuing in a number of places. When we take that information and we assess the overall situation, it suggests that as the outbreak evolves we are moving closer to Phase 5. We are moving closer to that, but I do not think that we are quite there yet. Phase 5 is a significant milestone in preparation for countries and in warnings, and what we are trying to do right now is to make absolutely sure that we are dealing with a sustained transmission in at least two or more countries. The analysis of the data, the analysis of the outbreak continues as we try to firm up this understanding and this information. Investigations continue  in many different countries as investigators in all these affected countries continue to try to collect information and analyse it as quickly as possible.

The science conference that took place today and which is continuing confirms the impressions that we have had to date and there is nothing that we have heard at the science conference that suggests that these preliminary assessments of what we are dealing with are not right. However, as always, we will continue to monitor the research findings which hopefully will shed new understandings on what we are dealing with and more detailed understandings.

The illness that we are seeing is generally consisting with seasonal influenza infection. That is the kind of symptoms that the milder cases are experiencing and generally what are seen  with other influenza viruses, although there is some suggestion that perhaps cases are developing diarrhea more often than is normal with seasonal influenza influenza or seen with seasonal influenza. So we will continue to follow this and see how the picture of clinical symptoms evolves.

The question that is really on many people's mind is what can we say about the severity of the illness at this point. I think that the information to date clearly points out that this infection can result in anything from very mild illness, where people do not need to be hospitalized and generally recover without any complications after several days, to fatal illness. We have now seen this occur in two countries and this is in keeping with how other influenza viruses behave. The question that we do not know right now is that when people get infected, how often are people going to develop mild illness, how often are people going to develop severe illness, and which groups of people may develop fatal illness. We do not have to handle on this right now and this is one of the questions which is important to identify. What is also important to identify is, among those people who develop serious illness, is there anything that can be done, are there any risk factors that can be identified, and so the investigations will continue in these areas.

At this juncture, I think that a fair question to ask is where we are going. Is it theoretically possible that this epidemic could certainly stop for unknown reasons, although this is probably unlikely at this point. It is also possible that we could continue on with spread of relatively mild illness in most countries recognizing that death and serious illnesses will occur sometimes. And it is also possible, that as we go into the future, we will see more serious cases. These options are all possible. We do not quite know how this is going to evolve but we will, as we mentioned over the last few days, monitor the situation very carefully. We will report the findings as they become available to us.

At this point I will stop the update. I wanted to just have a brief update today and we can move on to questions.

**Reporter from Mexico:** First of all, since yesterday, restaurants in Mexico City are not able to operate normally, only take away service. Is this measure advisable for Phase number 4 of the pandemic alert or it can generate a wrong impression in the society creating the risk that people are seeing this disease with the food. And my second question is, and this question was for the( …unclear…..) why Mexico is the only country reporting deaths at this very moment, while considering US reported a death today. Why Mexico?

**Dr Fukuda:** Whenever we have epidemics and pandemics occurring in countries or diseases outbreaks, the patterns may differ in different countries. Right now the picture appears more severe in Mexico than it does in many other countries, and national authorities do need to adapt their disease control strategies and actions to what is going on in the country itself. In this point, I think that the authorities are probably focussing on how to reduce the chance of infection when people gather together. In terms of the second question, why is it only Mexico that is reporting a significant number of deaths, the answer to this is that we do not know right now. It is clear that deaths can occur in other countries and serious illnesses can occur in other countries but most of them are being reported in Mexico. We do not know the reason for that, but this is one of the main focuses of the current investigation.

**Reporter from The Wall Street Journal:** I have a couple of questions. You mentioned that we are moving closer to Phase 5 but you do not think we are quite there yet. I just wonder if the Emergency Committee is meeting again today or tomorrow, probably not today but soon, to evaluate that. And secondly, I wonder if you could help us understand a little bit better the different numbers of deaths being reported from Mexico. I mean, clearly WHO is reporting only deaths that have been laboratory-confirmed by CDC or another lab. I am wondering if you know what testing capabilities the Mexicans can have right now, and so when they are saying they have 150 deaths or whatever numbers they are using, what level of testing and confidence do they have.

**Dr Fukuda:** There is not set time right now for the Emergency Committee to meet. Right now, the way that the Emergency Committee operates, and this is the Emergency Committee as convened under the International Health Regulations, is convened to provide advice to the Director-General of the WHO. At this point, there is very intense analysis of all available information going on, and when the Director-General feels that she needs advice from the Emergency Committee, then she will convene it. This is something that could happen on very short notice, it could happen later today, it could happen tonight, it could happen tomorrow, it could happen in a couple of days, or whenever the evidence suggests.

In terms of the different numbers of deaths, I think that one of the features that is simply to follow investigations especially when you have big outbreaks occurring, is that the numbers can be very confusing and you can have cases of disease reported, cases of deaths reported, and then some of them might be laboratory-confirmed deaths, and often times these are deaths which are epidemiologically suspicious but not laboratory-confirmed. I cannot address directly why do the numbers vary a little bit, right now, but I do know how these outbreaks unfold and how difficult and overwhelming it is to get the numbers quite straight. It is very common to have the numbers vary somewhat in the beginning of these large outbreaks. At this point, I cannot address the specifics, but that is generally, what is true with the outbreaks.

**Reporter from CBC:** The majority of confirmed cases outside of Mexico are among people who travelled solely to the resort areas places like Cancun, but the Mexican authorities are not reporting any confirmed cases in the resort areas in places like the Yucatan State, the Riviera. Could you please explain why that would be?

**Dr Fukuda:** I cannot specifically explain what is going on in Mexico right now, in terms of the epidemiology. I think it is still quite early in the overall investigations. Mexico is a very large country. The investigators are scrambling to map out what is the course and the distribution of the infections in that country. It is quite possible that there is this infection in many different parts of Mexico that have not yet been confirmed by laboratory testing, but we will have to see how this goes over the next few days to several days.

**Reporter from Asashi:** I have two questions. One is concerning the nature of the virus. I am wondering if you have any evidence that there have been mutations which turned from the pathogenicity and also the ability to transmit from human to human. And second question, concerning the core infection in Mexico. At previous briefings you mentioned that there might be a co-infection in Mexico and if possible could you name some of the responsible viruses or any other pathogens?

**Dr Fukuda:** The influenza virus that we are dealing with now, this swine H1N1 virus is a new influenza virus and so far, most of the viruses which have been, or all of the viruses which have been isolated and studied in laboratories, appear to be remarkably consistent and remarkably similar with each other. When you look at the genes, these are all genes from influenza viruses that have circulated in pigs before, so we consider it a swine influenza virus. Yet it is clear that this virus has somehow gained ability to infect people and to transmit among them. I think we are still too early in the investigations of the virus themselves to understand what kind of changes, what kind of mutations might have allowed this to happen. I think that in the future we should be able to talk more about what kinds of changes might have allowed this to happen, but right now, we do not have that information.

In terms of co-infection, just to maybe correct a misperception. We do not know of any co-infections that are also occurring with these swine flu virus infections right now. However, having said that, it is often true that when influenza infections occur, that there can be other bacterial infections which occur, which may lead to pneumonia or may lead to other complications. This is a typical finding for influenza viruses in general. However, right now we do not have any firm evidence of whether there is co-infections, or whether secondary infections occurring in the people who developed fatal cases or who had serious illness cases. This is something that, as investigations continue, I think will become clearer in terms of the clinical picture..

**Reporter from Canadian Press Agency:** I have a couple of questions if you would not mind. You said that it seems like the world is approaching Phase 5 but we are not there yet. The other day you talked about wanting to see, continuing transmission within communities where there have been importations of cases and we are seeing that, I think, quite clearly in New York City at the very least. What would trigger Phase 5 at this point. That is my first question. My other question is that, obviously the fact that the disease they have had in Mexico is quite mild is a very nice thing, but are you concerned that people may not take the possibilities of a pandemic seriously enough as a consequence and that they may not prepare themselves because they do not see this as a big deal.

**Dr Fukuda:** Right now, we have epidemiological information and a number of cases in a couple of locations. One of these is Mexico and another of them is New York City. In New York City what we have seen is clearly person-to-person transmission occurring in a large high school. This is what we often see with influenza viruses occurring in many different kinds of institutions. It might be nursing homes, it might be colleges, it might be high schools, and this is a typical from what we see, but what we are also looking for is whether we are seeing transmission of this virus out in the community itself. In neighbourhoods, not just those who are going to high school, but among people who are not necessarily connected with the high school. Ordinary people who are just going around. This is what we typically see with community level transmission of influenza and so this is the kind of information we are looking at before we really move to Phase 5. As I mentioned with one of the other questions, we are very intensely looking at the data as they come in and trying to get a handle on this.

In terms of the mildness of the cases out there and whether people may take a pandemic seriously or not seriously, I think the main point I want to make here, the most important point to make here, is that it is probably premature to think of this as a mild pandemic or as a severe pandemic, and it is very clear that we cannot predict what the cause of this will be. As I mentioned in one of the earlier interviews that we did, the worse pandemic at the last century started out mild in the spring time, it was fairly quiet during the summer, and then in the autumn when it really exploded, this is in 1918 and it was a much more severe form. And so we just know what the future is going to hold. The most important point, now, is that countries and organizations really have a warning, have time to prepare. There are a numbers of things to do, there are things that we have to look very carefully about: how we help with the development of vaccine, how we proceed with control measures and so on, but the important point here is that we have time to prepare ourselves, to implement actions, and this is what we want to emphasize.

**Journalist from Reuters:** We are wondering if you could elaborate a little bit more on what you have seen in terms of the transmission within the community. The Spanish health ministry has just a few minutes ago confirmed a case of swine flu in a person who had not travelled to Mexico. I wonder if you had any more information on cases that are not so-called “imported cases”.

**Dr Fukuda:** There are cases that are being reported which are occurring in people who have not travelled and one of the immediate question that comes up is: the people who become infected on one side, do they come in contact, are they associated with people who are travelling, and sometimes that has been seen and that is some of the kinds of questions that the investigators are asking. What we are looking for overall is whether we see many kinds of these infections occurring in a way that suggests that the transmission is occurring independent of travel, and it is being established in communities. That is the sort of pattern of transmission that really helps us to decide when an infection has become established in a neighbourhood or in a community, and then in country.

**Reuter from AP Geneva:** I think you suggest this issue of pigs. Today the parliament in Egypt ordered to slaughter all the pigs in the country. I am wondering it there is not perhaps too much misinformation still out there, that WHO isn't doing enough to combat, and in a sort of related question, regarding your information policy, we were told that if the Emergency Committee does meet today we would not be informed about what they decide until 2 p.m. tomorrow. That is a long time for rumours to go out, all kinds of speculations might make people do the wrong thing. Does WHO feel stifled in its ability to communicate directly with the public?

**Dr Fukuda:** In response to your second question, the answer is no. We feel very connected with providing information to the public. I think that this kind of daily briefing and all of the other interviews that are being done, really, are a testimony to that. One of the big pushes by WHO, but I think that many other organizations is to move the information out to people as quickly as possible. In terms of your first question, clearly it is helpful to put out as much accurate information as possible, this is the best way to combat rumours, best way to combat misinformation about pigs. In addition to WHO, there are a number of other organizations that are also working hard to put out accurate information. At this point, I want to make it very clear that we do not believe that the infections occurring in people are associated with getting infected from exposure to pigs. This is a different situation from what we saw with avian influenza – the bird flu – in which people got clearly infected by birds. In this situation, even though the virus originated in pigs, we do not believe that people are getting infected by pigs. This is really a virus that is being transmitted from person-to-person. Therefore, we think that with food-handling practices, the eating of pork meat does not pose a danger to people.

**Reporter from The New York Times:** Any efforts being made in Mexico to find exactly the origin of this outbreak. Is that being done, would it be an important thing to do, would there be any value to that at this point?

**Dr Fukuda:** It would be very interesting to be able to trace back and find out where the origin of this virus came from. This is one of the things that everyone is always interested about with a new disease. But I would say that at this point we have higher priorities. The most important priority in terms of investigations is to document what is going on now, how is the picture evolving: are we seeing infections in severe cases that are not being detected, are we seeing infection established itself in areas in which it has not yet been documented… this are the kind of investigations that are really critical right now to answer the most urgent issues of how is this evolving, where is it going, what is the impact on people, what steps might be taken to protect people. Nonetheless, I believe that at some point we should come back and try to understand what are the origins of this virus, both in terms of how it moved from pigs to people, where that might have happened. Very interesting questions but maybe not the highest priorities right now.

# Transcript of Virtual Press conference with
# Dr Keiji Fukuda, Assistant Director-General ad. Interim
# for Health Security and Environment
# World Health Organization
# 30 April 2009

**Gregory Hartl:** Welcome to the media briefing from the World Health Organization in Geneva for 30 April 2009. My name is Gregory Hartl. To remind you, an audio file and a transcript will be available of this press briefing shortly following. With me today is Dr Keiji Fukuda, Assistant Director-General at WHO for Health Security and the Environment.

**Dr Fukuda:** Thank you everybody for joining again this afternoon. I will keep the situation update relatively brief and just touch upon the most major points and go over the situation and, as then usual ask any questions anybody has.

As of 14:50 this afternoon Geneva time, the number of officially reported laboratory-confirmed cases of influenza A(H1N1) to WHO have been 236 cases. This is up from 148 cases that were reported yesterday. The largest jump in cases come from Mexico which went up to 97 cases, compared to 26 cases, which were reported earlier. The jump in numbers being reported by Mexico probably represents a lot of the work that is being done right now to go through the back log of specimens that have been collected from people with different symptoms. So they are going through several thousands of laboratory specimens right now trying to identify those that may be positive for the A(H1N1) virus. In terms of other important developments, last night is when the Director-General of WHO made the announcement that she believed that we should go from Phase 4 to Phase 5, and as of today that assessment holds steady and we do not have any evidence to suggest that we should move to Phase 6 today, or that any such move is imminent right now. In terms of the global epidemiological situation, I think it is fair to say that the situation continues to evolve. We see some countries reporting new cases. We also see that some countries in which infection has been going on are reporting continued cases and I think that Mexico is a good example. We have also seen that in other countries, cases appear to be holding steady, for example, the United States. At this time again, I want to repeat that there is nothing to us which epidemiologically suggests today that we should be moving towards Phase 6. Now, one thing that I did want to mention, because there is a great deal of interest about oseltamivir and antiviral drugs, that in 2005 and 2006 the manufacturer, Roche – which makes oseltamivir – donated 5 million treatment courses of this drug to WHO, and this was in the form of two different stockpiles: one was in the form of 3 million doses to support rapid containment operations (if WHO deemed that was necessary or possible), and then 2 million courses to be distributed out to Regional Offices in order to be provided to countries in most need. At this point, WHO has began immediately distributing these drugs to developing countries which are determined by WHO to be the most in need of this kind of assistance. The work of getting this out is now underway. In addition, there will be a portion of this stockpile that will be sent to Mexico to provide assistance to that country.

Roche has also indicated that it is both scaling up its production of the drug and is working with WHO to develop a framework where it can provide WHO with additional supplies beyond the currently available stockpiles, so that these drugs can again be made available to the developing countries most in need. The details are being worked out on this. At this point I think I will stop and see if there are any questions that I can answer.

**Reforma Newspaper, Mexico:** Do you think that from 10 to 12 days of quarantine or suspicion of the no-decision service, it is now enough, enough time for actually to pass the most critical stage. Do you think it is time enough?

**Dr Fukuda:** This is a very good question. Typically when we are dealing with an illness like pandemic influenza or regular influenza, the amount of time that you see people getting infected tends to differ in different parts of the country; that is, disease cases do not occur at all places in the country at the same time. Even in the modern world, where we see a lot more travel and people moving around a lot more, we continue to see this kind of pattern. Mexico is a pretty large country so it is quite possible that we will see different peaks and valleys of activity from this new A(H1N1) virus at different times. Now, we are still studying this virus, and how it spreads, and how long it may be established in communities and in towns or areas, so I think it is too early to say whether 10 or 12 days are enough days to slow down or reduce transmission in a neighbourhood. It is possible that longer time periods may be needed. It is also possible that depending on when those kinds of measures are put in place, they can dampen down the peak. For this disease and this circumstance, I think it is not quite clear right now.

**El Mundo:** My first question is to see if you could repeat the number of confirmed cases in Mexico for today. The second one is what is the WHO opinion regarding the recommendation from the President of Mexico that people stay at home these days of holiday. Is it a good idea or what does the Organization think about it?

**Dr Fukuda:** The numbers that have been officially reported to WHO as of 14:50 today Geneva time, are 97 laboratory cases of this new A(H1N1) virus and which includes 7 deaths. So those are the numbers from Mexico today. Yesterday the numbers that were reported to WHO were 26 laboratory-confirmed cases and 7 deaths. In terms of the kinds of recommendations being provided, one of the most important steps that people who may be ill can take, is really to stay at home when they are feeling ill and not to go work or not to go to school if possible. What this will do is both improve the care that they get – by staying at home they can get rested, they can get help from family members and so on – and it also will reduce the contact they will have with other people and perhaps reduce the amount or number of other people who might get infected by having contact with such people. So, this kind of measures can be helpful.

**Radio Canada:** What is the flu vaccine capacity worldwide? Do you delay the production of vaccine because the virus could still evolve or is it because of a lack of capacity that would impede the production of the seasonal flu vaccine.

**Dr Fukuda:** I don't have a precise estimate of the total vaccine capacity right now, but it is approximately about 500 million doses of regular seasonal vaccine that can be produced by the combined production capacity around the world right now. What is a little bit difficult to estimate however, is that how much this kind of production capacity translates into the production capacity for a potential pandemic A(H1N1) vaccine, because the technologies have gotten better and there are newer ways to make vaccines, which may stretch out this supply. That is roughly the capacity to make seasonal vaccine but I cannot give you a precise estimate right now about how that may translate, or how much potential pandemic vaccine that can be made. At this point, it is not a question of delaying the production of the pandemic vaccine or of an A(H1N1) vaccine for this virus. In order to make a vaccine against a new virus, such as this new A(H1N1) virus, you have to go through several different steps, and going through these steps takes months of work even when you accelerate the pace at which you are doing them. For example, you have to take the viruses that have been collected from people who have gotten ill, you have to do several steps and a laboratory to turn it into a virus that can be used to make vaccine, and then the vaccine manufacturers have to see if they can work with that virus, if it works well with their production systems, there are safety checks on the viruses to make sure that there are no obvious dangers to using that virus. It also requires time to actually produce the vaccine. All of this work combined even when companies and the other public health laboratories are working around the clock, really takes some months of work to do.

**National Public Radio:** First question is, you had said in yesterday’s and earlier briefings that what you were looking for before you are moving to Phase 5 is evidence of transmission in the community. You said: ordinary people just going around and not just close contacts. What specifically was the basis then from moving from Phase 4 to 5. The epidemiological picture is still very unclear to the public and the information flow is slow. Is there evidence that WHO had last night of community spread up that schools and families, that did convince the Director-General that this needed to be done. And secondly, why if you know and can you explain why deaths in Mexico were 20 confirmed deaths, laboratory-confirmed presumably, and then 7 and then no increase despite all the testing. What does that represent?

**Dr Fukuda:** Let me just review the Phases a little bit and explain how we look at them, and what the information today tells us. The difference between Phase 3 and 4 is that in Phase 3, we see an animal virus – a virus like the avian flu that we saw before – able to infect people, but it doesn’t really transmit. With this new influenza A(H1N1) virus we went to Phase 4 because it was a new virus to people and we thought it was able to infect people quite easily, more easily than the H5N1 than we saw before circulating in many different regions among birds. That was the evidence which told us we thought we should go to Phase 4. Phase 5 represents a spreading out of the virus in a way that we are seeing sustained transmission going on in countries, not just travellers bringing infection to a country and then nothing happening. WHO looked at all of the data that were available to work, and these were the cases being reported by the countries that you know about, the travel-related cases and also the cases being reported in Canada and in the United States. We also had discussions with a number of different scientists from around the world, which was done yesterday in a large global conference, and then we also talked with the health departments doing these investigations; and then in addition, there was modelling work which was being done by some of the scientists that are working with WHO. It was on the basis of all that work put together, which indicated quite strongly that what we were seeing is sustained transmission going on for multiple generations and the overall picture was not really possible to explain in any other ways. There was no alternate explanation for what we were seeing. Now, when we look specifically at the countries, particularly in Mexico, and also what was going on in New York City, what we began to see was an emerging picture where this virus was really beginning to act like an influenza virus, like a human influenza virus, establishing itself and in the areas, and really seeding itself in these areas in a way which suggested that it really was becoming part of the community, not just travel-related cases. And so it was on the basis of that overall analysis, looking at all of these considerations that the Director-General made the judgement that this was now the time to increase this pandemic Phase from 4 to 5. One of the things to understand about pandemic Phases that is really important, is that these Phases are not intended to be a barometer of epidemiology per se. This is not a measurement of the epidemiology per se, but it is really a warning and an alert to countries and to the global populations, that the risk of this new virus spreading and reaching their countries is now judged to be significantly higher and it is really a call for governments and people to really take stronger preparations, to move ahead and take the preparations that they need to in order to reduce the health impact of the new virus. In terms of the numbers in Mexico, I think that right now the investigations in Mexico are looking at a very large amount of data: they are looking at laboratory specimens, a large set of numbers in terms of disease cases, and we are trying to match up those pieces of information, and right now I think that mainly what is needed is time by the investigators to take a look at the disease cases, to go through the tests which are done. As I mentioned, there is backlog of several thousands of specimens which have to be tested. Some of these specimens may come from serious cases, some of them may come from mild cases, and some may come from other people who have died. After they go to the testing and they can match it up with this kind of information, I think we will have a better handle on how many of these may be associated with death or with serious illnesses. So, until the investigators really have more time to go through and complete those kinds of analyses, it is a little bit premature to try to understand more fully what these numbers mean.

**Le Temps, Switzerland:** I would like to hear you about the modellisation of WHO on the ground in the regional offices. What does this really concretely consist of?

**Dr Fukuda:** WHO is an organization that is spread out in many different countries and the way WHO is put together, it has country offices and regional offices, and several programmes located at the Headquarters in Geneva. WHO simultaneously tries to address several levels of activities when dealing with a large complicated emergency like this. For example, in a country office, which are run by WHO representatives and the staff that are there, they will be working directly with the staff of Ministries of health and then with technical agencies to help conduct investigations, to help cope with the data, to help identify needs for the countries, to act as a liaison between the countries and the international partners who may be able to provide assistance, and to coordinate international systems that may be available for the country. This is where WHO really hits the ground and is running really hard: it is at the country office level where they are working side by side with the colleagues from the country. These are the kind of activities that they typically do and these may help with the communication, provide guidance – the guidance is rarely available – help find that guidance and try to provide that kind of assistance, The regional offices also do the similar kind of activities but at a regional level and try to coordinate what is going on in any of the six WHO Regions. At the WHO Headquarters level, we also do again in a similar concept, but the context are being made between the large international organizations with many of the countries different donors who may have resources available to provide to the countries that need them the most. What we are able to do at this level is to contact and coordinate and put together all the scientific resources to pull together the best information. All of these sorts of activities are going on simultaneously. They are really geared towards the same thing: how do you get assistance to the countries that need them the most, where do you find resources, what sorts of gaps are there, how do you meet them, and then how do you coordinate the international approach to try to provide assistance. It is a complicated mix of activities going on and at several different levels but the idea is very simple: get help back to the countries that need it the most.

**Time Magazine:** We are now at the end of the flu season in the northern hemisphere but of course that means it is coming up in the southern hemisphere. What will happen if this does begin to spread in the southern hemisphere countries and on the top of that, should they be allowed or should be thinking about structuring travel restrictions to protect themselves since they may be at a greater danger rather than those in northern hemisphere now?

**Dr Fukuda:** We are coming to the end of the influenza season in the northern hemisphere and the season will be starting up in the southern hemisphere. It is particularly important now to pay attention to what is going on in the second hemisphere. Even when you have the introduction of a new influenza virus as we are seeing now, it still usually follows some kind of seasonal activities. For reasons we don’t fully understand, in the winter months of the northern hemisphere we tend to see more activity in the northern hemisphere, and in the winter months of the southern hemisphere we tend to see more activity in the southern hemisphere. So it is possible that we will see outbreaks of the A(H1N1) virus occurring more frequently in the southern hemisphere than in the northern hemisphere. This is what we have to be watching out carefully for. In terms of travel restrictions, we have discussed earlier that WHO does not believe that travel restrictions will help slow down the movement of this virus and that has to go for the southern hemisphere as for the northern hemisphere. We do very much think that all steps should be taken to protect people. In terms of travel, again the two most important pieces of advice are that if you are feeling ill, before you begin travel or before you begin air travel, you should strongly consider to delay that travel and stay at home until you are feeling better and not symptomatic, and if you are travelling and you become sick during that travel, you move from one place to another, and you get there and you are not feeling well, it is important to seek medical attention so that you can be taken care of. These steps will help ensure the safety of people who are getting ill. We will also not disrupt travellers, it will minimize the disruption to travel. This is the advice that we will provide at this point.

# Transcript of virtual press conference with Gregory Hartl, spokesperson, and Dr Marie-Paule Kieny, Director of the Initiative for Vaccine Research World Health Organization

## 1 May 2009

**Gregory Hartl:** Welcome to WHO's daily 17:00 o'clock briefing. My name is Gregory Hartl, I am the Spokesperson for WHO and next to me is Dr Marie-Paule Kieny, the Director of the Initiative for Vaccine Research in WHO, who will be giving you a technical briefing in a couple of minutes on pandemic vaccine development. First of all, I would just quickly like to summarize the latest figures we have as of 14:20 GMT, it's about 45 minutes ago. We had 11 countries officially reporting 331 cases of influenza A(H1N1) infection with 10 deaths. They come from the following countries: United States has 109 cases with 1 death; Mexico has 156 cases with 9 deaths; Austria 1 case; Canada 34 cases; Germany 3 cases; the Netherlands 1 case; New Zealand 3 cases; Spain 13 cases; Switzerland 1 case; United Kingdom 8 cases. Thank you very much. I now turn over to Dr Marie-Paule Kieny.

**Marie-Paule Kieny:** Good afternoon, good evening, good morning. It's a pleasure to do this first briefing on vaccine against influenza A(H1N1).

Why are we so interested in vaccines against this new virus? It is because we all know that vaccines are an extremely effective public health tool and in addition, vaccines against seasonal influenza are protective against the death – in severe disease – of millions of people every year. So, therefore, it is generally recognized and accepted that it would be critically important to have a vaccine if you want to stop the pandemic that might be coming with this virus.

Let me first go into the development of this new vaccine so that you know where we are in this development, and let's just deal with this issue of knowing whether the seasonal vaccine, as it is, would be effective against influenza A(H1N1). As you know, some of you know, the seasonal vaccine is composed of three components, and one of these components is also called H1N1 and this virus has been circulated in the human population for many years, but it is quite different from the one that is circulating now. But in order to assess whether vaccination with seasonal vaccine would be effective or not, serum from vaccinated people has been tested by the US CDC in Atlanta, and for the time being, the results show that there is very little chance that seasonal vaccines as they are used in their vast majority in all countries of the world, would be effective against this particular virus. Why do I say “in the vast majority”? It is because there are still tests going on some very specific preparations that have been made, using what is called an adjuvant or (….) adjuvant that is a “booster” if you wish for a vaccine, and on serum from people who had been vaccinated against seasonal influenza with vaccine containing this booster. The serum from these people is still testing at the US CDC and we will know in a few days whether this particular seasonal vaccine could be potentially protective against influenza A(H1N1). Apart from that, the current opinion and consensus of the experts and the scientists is that there would be no protection awarded by this vaccine. Now, why are we sure that a new vaccine will be successful? Are we sure that we will get a new vaccine? As you know, for some diseases, it has been painfully slow to develop vaccine – like HIV for example. I think that for this particular vaccine there is no uncertainty because there is tremendous experience in the vaccine industry to make vaccine against both seasonal influenza and also against the avian H5N1 virus. Those of you who followed this topic might know that it was initially very difficult to make vaccine that are thought to be effective against H5N1, and that the industry has succeeded in making it.

So based on these two pieces of extensive experience, we have no doubt that making a successful vaccine is possible within a relatively short period of time. What is a relatively short period of time when a pandemic is imminent? Of course, we would like to have a vaccine tomorrow, we would have wanted to have it yesterday. The reality is that from the time the potentially pandemic virus is identified, it takes between 4 to 6 months to have the first doses of vaccine coming out of the factory and be available for immunizing people.

Why does it take so long? Well, it's a long journey. Even if you know by heart all the steps, you know that you are going to get there, it is still a long journey.

So what are the main steps? You first need to isolate the virus, this is done. Then, when you have a virus, you need to adapt it to make vaccines, you need to tweak it. And these steps, which are going on now at the US CDC as well as in many WHO Collaborating Centres, are to adapt this virus to produce vaccine. This will be done, we think, by mid- or end of May. So then, the starting material to make vaccine will be ready. It will immediately be shipped to the manufacturers, and the manufacturers will immediately put it in their laboratories and fine-tune to adapt it to their particular production methodology. After that, they will inoculate eggs. Indeed, the technology to make influenza vaccine is based on the inoculation, with virus, of embryologic eggs – or of cell culture but it is not so important in terms of volume right now. Then, they let the virus grow in the eggs, they harvest the virus in the eggs; they need to kill the virus because of course, you don't want to inject live virus to the population and they do then what is called “formulate”. They will mix it with various of these boosters and they will make various formulations, as it is called, with different levels of dosage. All these candidate vaccines – we are at the stage where we have candidate vaccine that can be tested in humans – will be submitted to very strict quality control and will be evaluated in humans through clinical trials. Why is that? It's because if you inject a potential vaccine in a mouse, the response of the mouse doesn't tell you anything. It doesn't tell you if it will work in human. So the obligatory step will be to test it in humans, in clinical trials, and following this, national regulatory authorities will need to register to put their approval on this vaccine before it can be made available to all. This is absolutely mandatory and obligatory because by no means do we want to compromise the safety of otherwise healthy people by inoculating them with a product that would not have all the guarantees of safety and quality. These are all the reasons why it might take, it will take, between 4 to 6 months between the time the virus is isolated to the availability of the first dose. I'm very happy to listen to and try to answer to the best of my possible knowledge to any questions that you might have.

World Health Organization

# Transcript of virtual press conference with Dick Thompson, WHO Spokesperson, and Dr Mike Ryan, Director of the Global Outbreak Alert and Response Network, World Health Organization

## 2 May 2009

Hi, everybody thanks for joining us. I apologize for being a little bit late but I think you may understand things have been a little hectic. We are May 2, today's guest for this video press conference is Dr Michael J. Ryan. Dr Ryan, is the Director of the Global Alert and Response team. We are going to do this the way we did it yesterday we will ask questions on line and questions here in the audience. As usual, we will have a transcript up and on the web and we are also going to be posting the audio version. Dr Ryan will begin with a brief statement and then we will take your questions. We expect this to last about a half hour and not longer, thanks. Dr Ryan.

**Dr Ryan:** Welcome ladies and gentlemen and thank you for coming to this press conference and my apologies for being a few minutes late. I would like to give you an update on what has happened today and talk a little bit more after that about the seriousness of the pandemic and would like to talk about how WHO is responding to the situation as we speak. We are still at phase 5, the WHO pandemic alert level. We continue to see an increase in laboratory confirmed cases as of 6 am GMT today, 15 countries have officially reported, 615 cases of A(H1N1) influenza infection with 17 deaths. Mexico has reported 241 new laboratory confirmed cases and 7 new deaths since 23:30 GMT of 1st May. The increase figures from Mexico reflect primarily ongoing testing of previously collected samples and not a surge on people falling sick. We have seen case reports from Hong Kong and South Korea indicating the geographical spread of the disease. But we have no evidence of sustained community spread outside North America.

I would just like to speak a few words about what a possible move to Phase 6 might mean. Pandemics are serious, but it is important to know that Phase 6 describes geographical spreads of the disease and not its severity. We do not know how severe or mild this pandemic might be. History has shown us that disease activity in the past pandemics is like a patchwork, while every country is ultimately affected the state of the development of the epidemic in any given country can be very different at the same time. Therefore measures being taken by governments will differ, depending on the state of the development of the epidemic in that country. This is the time for us to prepare and be ready. WHO continues to monitor the spread of this virus and expand our understanding of its behaviour and severity. We are also moving to a more operational stance to support countries in the readiness and response in collaboration with other UN partners, our technical partners around the world, collaborating centres, NGOs and others. We have begun to dispatch 2.4 million doses of antivirals to 72 countries including Mexico from stocks donated by Roche in 2005 and 2006. We will also supplement our regional stock piles in the six WHO Regions as a contingency for further supplies to countries. The Director-General is continuing discussions with Roche and others on how to best meet future needs of developing countries for antivirals.

On the diagnostic front, the WHO Collaborating Centre at the Centre for Disease Control in Atlanta is today dispatching diagnostic kits to all influenza reference laboratories for further dispatch to national reference laboratories as needed. We have teams on the ground in Mexico continuing to work with the Mexican authorities to improve the quality of data being collected, improve the quality of analysis of that data. On a day to day basis, this is the business we do. We monitor, evaluate and respond to roughly 250 public health events a year, many of which do not reach the news. But some have implications for global health security. Obviously the biggest thing we face now is the possibility of a pandemic, good preparedness will help us mitigate its effects, should we work together in a coordinated and collective fashion. Thank you. I can take some questions now.

**John Zarocostas, the British Medical Journal:** You just mentioned your dispatching 2.4 million doses to 72 countries. How many of these countries are least developed countries with the poorest health systems, are they going to get priority given the weakness of their infrastructure?

**Dr Ryan:** Yes, all of this drug is targeted at the poorest countries with the greatest needs.

**Andy Edcart, NBC news:** The European countries have been reporting some increase in laboratory-confirmed cases. Do you see any sign here that this could be the region that could trigger possibly or indicate that there could be a raise to Phase 6?

**Dr Ryan:** I can confirm that in the European area, France has confirmed an additional 1 case today totalling 2, Germany has confirmed 2 additional cases, the UK 2 further additional cases and Spain has confirmed another 2 additional cases and Israel 1. And those figures will be updated in our daily update at 19:00 today. Those figures are not reflected in the figures as released this morning. But I think what you need to see there is a very small number of cases, is very limited, the countries have done an amazing job, number one to detect those cases, they have got people to hospitals, they have put people on treatment and they are following up on contacts. So I think it would be, at this stage, unwise to suggest that in any way that those events are out of control or spreading in an uncontrolled fashion. I think the next few days will tell as this develops but at this point, I could not agree with you.

**Bloomberg:** Were we yet to pinpoint this exactly how this swine drive evolved, can you expect it with more intensive livestock production, we could see more instances of enzootic viruses causing widespread disease in humans?

**Dr Ryan:** I think this is phenomenon we have all been observing over the last number of years. If we look at major threats to international public health security over the last three decades, many have emerged from animal origin and diseases that breach the species barrier can establish themselves on humans, we have seen this with SARS, we see this with haemorrhagic fevers like Ebola, Marburg and other diseases. And this is something that remains poorly understood, and something there is always that risk that these diseases can cross that species barrier. The animal/human interface needs to be watched carefully and needs to be managed through the proper risk management and collaboration between the animal and human sectors. In the particular case of the current outbreak, we have seen in the past, on occasions disease can spread from pigs to humans, but in generally ends and dead ends with one or two cases, in this case we see a virus transmitting in human populations and there is no evidence at this point that there is transmission from pigs to humans, its very important to restate that and that people understand how to protect themselves is to prevent being infected by another individual and not to be concerned about being infected by pigs.

**Helen, Canada:** I was wondering if you could tell me the World Health Assembly is coming up in a couple of weeks. I think hundreds of health ministers and people in their entourage will be descending on Geneva, which is, you know, quite a large gathering and I am wondering if WHO is reconsidering how wise that is at a time like this because they could make the SARS distribution schematic from the Metropole hotel look tiny?

**Dr Ryan:** Thanks. At this stage WHO has no plans to cancel or postpone the World Health Assembly. But, when it comes to mass gathering events in general, these are decisions that individual governments and organizations will obviously be faced with over the coming weeks. We have virtual advisory group of experts in managing the risk associated with mass gatherings and recently issued guidance on mass gatherings in general in relation to epidemics and as we speak we are developing some basic guidelines for countries right now so they can use those guidelines to assess in the coming weeks and months, whether mass gatherings are advisable or not. I think it is important though to remember at this stage as I said before the epidemic would be at different stages of development in different countries with different risks. There are different local risks and there are different global risks, so each individual event must be assessed on its own merits and we will be assisting countries with the advice they need to make those decisions. But I can reconfirm that there are no plans to cancel or postpone or curtail or limit the World Health Assembly, it is a very important opportunity for global health leaders to come together and address the issues around this pandemic and other very important health problems that we face in the world today.

**Deborah**: Just a clarification: on the 72 countries, can you explain how did you get to the 72 countries? Are the government asking for them? Are these countries all from the developing world and a little over 2 million doses seems very little to 72 countries?

**Dr Ryan:** In terms of these countries they are very low resource countries in the world and the ones who are most vulnerable. We are also establishing what stocks countries already have, so there are a number of considerations in that dispatch. 2.4 million treatment courses reflects a large part of a rapid containment stock pile and that stock pile had been reserved for the purposes of containing the virus rapidly should that have been an opportunity. Having determined that such containment is not possible, WHO has decided to dispatch that to countries in order to assist them in their preparedness and readiness. Many countries have access to their own stocks and as I said, the Director-General is working with Roche and with other companies to establish how much more antivirals can be identified and transported. But we believe, at this point it is important that all countries have access to some antivirals in order to treat severe cases should they occur.

**Jason Gale:** Just based on the cases confirmed so far, what is your epidemiological data telling you about the severity of disease and are you still seeing a bias towards otherwise healthy young adults in their 20s, 30s or 40s getting severe illness?.

**Dr Ryan:** We are seeing disease across all age groups and certainly Mexico is the country which has the most developed epidemic and we certainly see about half the cases are under 21, half the cases are over 21 and it is spread across the different age groups.

In terms of severity, part of the issue here is trying to look at the Mexican epidemic vis-à-vis the other outbreaks and this determination that it looks more severe in Mexico. I think you can see today that the Mexican authorities, in looking at their data, have now confirmed that 17 of the deaths were laboratory-confirmed and still have to wait and see how many of the reported deaths will ultimately be assigned to a laboratory diagnosis of A(H1N1). So severity is not completely established from that perspective. It also reflects possibly that in Mexico we probably have had this virus spreading for a very long time, so the number of people who have been infected and mildly sick maybe much larger than we previously suspected. And therefore, the deaths we are seeing may reflect the small proportion of deaths to a very large event and what we might be seeing is a very small number of deaths in other countries reflecting small numbers of cases so far. So I think we have to be very, very careful in trying to make an accurate estimate of severity. We are working with disease modellers, we are working with epidemiologists to get a better handle on that but I think if you cast your mind back to SARS, if you cast your mind back to other epidemics, at this stage in an epidemic it is sometimes very difficult to make an accurate estimate of severity. We will give you that as soon we have something that we can stand over.

**David Brown, Washington Post:** Getting back to the last question, are there any very early estimates of case fatality rate and in particular, fatality rates in pregnant women who I believe are traditionally the most vulnerable group in the influenza outbreaks.

**Dr Ryan**: No, we do not have any specific data on pregnant women and what I would like to do is not deal with this question until the next 24 hours when I believe we will have better estimates of case fatality, or at least ranges of case fatality that we can determine. But at this stage, I want to leave it to the teams working on the epidemiology assessment to complete that epidemiology assessment so that we can give you a better figure, and again even when those figures are given, those figures may change.

**Reuters**: I wonder if you can tell us about how things are in the SHOC Room now if there is a sentiment that things are a bit calmer in recent days and how has that been?

**Dr Ryan**: As we call it the SHOC Room – the Strategic Health Operations Centre – is the nerve centre where all of our data information and various task teams work out of. I would have to say that there are now hundreds and hundreds of people within our Organization fully committed to the response to this disease and working in a number of task forces focussing on; global tracking, monitoring, risk assessment and disease evolution, working on a vaccine task force, working on an antivirals task force, working in a communications task force. And also, a science and knowledge and standards group that is really focused on our understanding of this disease, and this group is connected to a virtual network of modellers, epidemiologists around the world and there will be further scientific consultations on Monday and Tuesday in smaller very expert groups looking at this data from Mexico, from the US and elsewhere.

We also have a growing field operations and country support group working with and through our Regional Offices which combines the skills and field capacities of our programmes, our programme on Global Alert and Response, our sister programme in Health Action and Crisis who deal normally with the floods and humanitarian settings, our colleagues in the Polio Eradication Programme who have proven their capacity to support countries over the years. So what we are seeing within the Organization is, in my view, an ability to surge and turn the capacities of the Organization onto an urgent problem – very, very quickly at all levels of our Organization.

Now, having said all that we are tired, the odd loud word is said, but what we have is had lots of practice unfortunately, with SARS, with tsunamis, with major responses to epidemics. We vaccinate millions of people every year in response to meningitis epidemics, we can move millions of vaccines and we can mount mass campaigns to vaccinate people, we can contain outbreaks of Ebola in the rain forest. So we have that capacity to assist countries but epidemics of the nature and the response to them does create stress. We are resting our staff and we have operational "on" and "off" periods and we know this maybe a long haul. In SARS we got very tired and many of us appeared to have reached burn-out, this time we intend to be able to maintain this pace for as long as is necessary to provide our public health service to our Member States and to communities.

**John Cohen, Science Magazine:** Are there any cases where there are probable or confirmed cases of hospital transmission? When we moved from Phase 4 to 5 it seemed as though the sensibility was that Phase 6 was inevitable and just a matter of time. I am hearing something a little different; have you shifted your perspective about that?

**Dr Ryan:** I didn't quite catch the meaning of the last part of your question but in terms of health workers, there have been reports of health care workers affected. I am struggling to remember, I believe in the UK, Germany, but I would have to check that and get back to you, but we have had confirmed reports of this disease in health workers. It is important to remember that our health workers are in the frontline, they are caring for the people who are sick. And they are the ones most at risk in many ways, of becoming sick themselves. They need more than us in Geneva – sitting in our SHOC room – they are at the frontline of this epidemic response. We need to do our best to protect them in their daily work and support them as they care for the victims of this disease.

At the present time I would still propose that a pandemic is imminent because we are seeing the disease spread to other countries. We have not seen yet that sustained transmission outside one WHO Region. At this point we have to expect that Phase 6 will be reached. We have to hope that it is not reached.

**Telery Tamera, NHK, Japanese broadcast:** I want to make sure again that so far in Europe there is no evidence that there is no sustainable community infection?

**Dr Ryan:** Yes that is true. There have been some secondary cases, but again in very close situations where family members were closely associated with cases, and we have seen that with H5N1. We are talking about here is sustained-community transmission in the general population where it is very, very clear that the disease is spreading far within that community. Not within close family, cluster-like situations. It is very important to make that distinction before we announce a sustained process.

**Question:** Many Asian countries worry about the spreading of this disease. Especially about first occurring in Hong Kong and South Korea. What do you think about the recent situation in eastern Asia?

**Dr Ryan:** Fortunately, some of the best prepared countries in the world will probably be in eastern Asia, after that last number of years and the high level of alerts where preparedness in eastern Asia for a possible pandemic of H5N1. And I think the authorities there have no more than ourselves learned through SARS how to deal with large public health emergencies. So I have every confidence that Asia will perform well in such a situation.

**Brian Walsh, Time Magazine:** I know it is still an evolving situation but at this point are there any lessons you can draw from this initial response from discovering as far as from mobilizing the pandemic alert system, especially for the Global Outbreak Alert and Response Network? Obviously this is the first real test since SARS. What are the lessons you have learnt so far?

**Dr Ryan:** One learns lessons every day. To be honest I have not had the time to step back and think like that. But I would like to say that what we have seen, if you compare this to previous events, we have seen remarkable amount of openness and transparency and cooperation between countries. We have seen countries taking their obligations under the International Health Regulations very seriously; we have seen collective action; we have seen sharing of information; we have seen international support from Mexico, from epidemiologists, clinicians and others from the Global Outbreak Alert and Response Network. So we are doing things better, as an international community. We have challenges that we are going to face collectively in the future. And those challenges are going to be: how do we ensure that the most sick have access to antivirals; how do we ensure those most vulnerable get access to vaccines when they become available. So there are major issues that we will face. From an operational right now, I am reasonably content with the performance of our Organization and of our partners. We will take stock at the end of this, every action we are taking, every e-mail we are sending, every note we receive is being triaged, logged in our event management system. We are going to learn from this event, even if it takes a long time to finish with it.

***Dick Thompson's addition:*** *And I would like to add, even if you might be a bit reluctant, but this is our business really, and WHO mobilizes to handle sudden emergencies. We do this very often, whether it is Ebola (haemorrhagic fever) in Africa or the Tsunami spread over a very wide area. Some countries fortunately can deal with a crisis once in a century. As Mike pointed out we deal with 250 events a year. And that isn't just reporting an event, that is responding to an event.*

**Brad Clapper, Associated Press:** Scientists at the CDC seem to be saying that the study of the genetic properties of this virus seem to suggest that maybe it is less deadly than was originally thought. That it lacks maybe some traits that were in the Spanish flu virus, or in the H5N1, that make it less deadly than maybe we had feared a few days ago. Does WHO share this assessment? And what can you tell us about an assessment of its genetic properties?

**Dr Ryan:** First of all, I have to admit that I am not aware of that specific report. I am sure that people on the science group are. I would be very pleased if it turns out that this virus is weaker than it could be, I would be the most happy man in the world. However, I think that history has told us that these viruses are very, very, very unpredictable. And this virus is spreading in human populations, these viruses mutate, these viruses change, these viruses can further reassort with other genetic material. So it would be imprudent at this point to take too much reassurance from studies as that. However, any evidence that pushes us towards being able to issue statements on less severity will be very reassuring for the world.

**Jaime, Sao Paulo, Brazil:** How do you respond to the Mexican authorities that criticize the delay in the WHO's response. If you can perhaps go with us through the process that it took – if it is not too long, of course. And secondly, again on the 2.4 million doses, is there a region that received more? Did you divide 2.4 million by 72, can you give us a little bit more detail or perhaps a list of the countries and how much each one received?

**Dr Ryan:** In terms of the second part of your question, there is a document currently being drafted for release on that. I think it may be released tomorrow which will detail that process. I think it is better rather than my giving you wrong information, that we wait for that analysis to be dispatched.

In terms of chronology of events, yes we can certainly go through that. We do maintain very detailed records of all our communications with countries. WHO primarily receives information from two major sources:

1) formal sources: official reports of governments to us under the International Health Regulations (IHR);

2) but we also receive information, and scan information from multiple informal sources. The primary one being the Global Health Intelligence Network which is a joint project with the Government of Canada and the public health agency, which has been the core of our epidemic health intelligence gathering for the last decade.

We have teams at country level, at regional level and at Headquarter's level who constantly exchange information on likely events that may be picked up, either officially or unofficially reported. If we pick up those events, we carry out an immediate risk assessment and on the basis of that risk assessment, immediately seek verification from the affected country with specific questions relating to the disease, the type of disease, the spread, number of deaths, and also offer assistance with any verification to assist the country with investigation or response should that be needed. That is a daily process. All of that information is maintained within a sophisticated event management system through the levels of the Organization. And on the basis of the information we receive, we can carry out further risk assessment and decide whether or not an international response needs to be offered or delivered to contain the disease.

I think you are particularly interested in Mexico, in terms of the government’s perceived criticisms. First of all, I have no criticism of the government of Mexico, they have been dealing with a very complex situation, and difficult epidemic, and have been exceptionally responsive to requests for information from WHO.

We will try and get an exact chronology and get that out to everybody in terms of exactly the chain of events. But if I want to be quick:

- 10 April 2009: the Global Public Health Intelligence Network sent a report to AMRO/PAHO – as many of you know, our regional office for the Americas – saying that there was a rumour of acute respiratory syndrome in Vera Cruz in Mexico. They reported that all clinical cases were recovering and that there have been no cases since the 3rd April and that the epidemic was over. This was unusual because it was a large epidemic of respiratory illness at the end of the influenza season, but they had already investigated that event. When we asked them to verify the event, they had gone there, they had investigated the event, the event was over and nobody had died and all clinical cases were recovering. That was the report we received.
- 11 April: we requested a verification based on our risk assessment.
- 12 April, morning: the IHR focal point in Mexico sent a detailed report of the investigation of that event.
- 16 April: a further rumour was picked up from media sources of a non specified atypical pneumonia cases in a hospital in Oaxaca state in Mexico. The interest in this for us was that the initial report was that of a coronavirus. Coronavirus is the virus that causes SARS.
- 17 April: verification was officially requested from the government of Mexico through the IHR national focal point. Two and a half hours later, the Mexican government responded with a report to say that this was not an outbreak, that this was a single severe case of pneumonia in a middle-aged lady with underlying conditions. The initial coronavirus positive result had been carried out in a private lab, the follow up testing of

respiratory samples were negative for coronavirus influenza and other common respiratory viruses.

- 19 April: we notified Mexico regarding the cases that have been occurring in California.
- 20 April: a teleconference was organized by CDC with Mexico and our PAHO team to discuss the situation in California and to update them on the information from that Oaxaca case.
- 22 April: WHO received official information through the IHR national focal point of reports of severe pneumonia associated with influenza, reporting an unusual increase in cases of seasonal influenza during March and April 2009, the peak of influenza usually occurring at the end or the beginning of the year.
- 23 April: the national focal point further confirmed report of 47 cases of severe pneumonia out of which 12 have died between 18 March and 18 April.
- 25 April: laboratory results related to the cases of Mexico, the Mexican authorities had sent samples to the public health agency of Canada Winnipeg laboratory and those samples were positive and those samples were immediately reported to the World Health Organization. I received the call at 3 a.m. from the Assistant Director-General who had just been contacted by Canada on the telephone, and 22 minutes later our operation centre was open.

I am quoting from a very detailed chronology and am trying to give you the highlights. There is much, much more information documented and we will be very pleased maybe to try and put together a more detailed chronology and let you see how things developed. But it is very important to remember that, at no point were Mexican authorities not wanting to work with the WHO, not responding to our request for information.

**New York Times:** Authorities in Mexico are reporting that there are many suspected cases, fewer than half now are coming up positive with the test that were given to them by the CDC. Could you tell us what meaning if anything this has about your perception of this outbreak?

**Dr Ryan:** There are many things that can lead to an outcome like that. Many times, in a situation of an outbreak and particularly one of these very high profile, sometimes you get the worried or other people reporting illness and they get tested and they are obviously negative. So it may just reflect the fact that many people who do not have influenza are being tested. It can sometimes mean, yes, that there are problems at the laboratory level, so it is very hard to make such a determination and I have to know more details. And in some cases, in other epidemics, we have seen this in Africa with the Ebola and Shigella, you can have mixed epidemics. In this particular case, I do not think that this is the issue, but there are many number of reasons why you see a change in the proportion of cases who become laboratory-positive. I would have to have much more information to make a comment. I will be happy to follow up with you on that afterwards if you want.

World Health Organization

# Transcript of virtual press conference with Gregory Hartl, WHO Spokesperson for Epidemic and Pandemic Diseases, and Dr Peter Ben Embarek, WHO Food Safety Scientist, World Health Organization

## 3 May 2009

**Gregory Hartl:** Thank you very much for joining us today for our regular 5:00 pm daily press briefing. Just before I hand you over to Dr Peter Ben Embarek who is a scientist in our Food Safety Programme, I will remind you that we are still at Phase 5, and as of today, based on this morning's numbers, we have 787 confirmed cases coming from 17 countries.

**Dr Ben Embarek:** Good afternoon, good morning. Yesterday the Canadian Food Safety Inspection Agency had announced that they had found the influenza A(H1N1) virus in a swine herd in Alberta and it is believed that this herd was infected through a farm worker who had been travelling to Mexico and on his return he worked on the farm and probably infected the animals. It happened on the 12th and 14th of April, and about 18 days later the swine started to show symptoms. They are all now recovering, including the farm worker, and it appears that the disease is also showing a mild form in the animals. It is not a big surprise. I must say that we suspected that at some point, since this virus has swine virus elements, that we would find possibly the virus in swine or pigs in the region where the virus is circulating. It is also clear and necessary to re-emphasize that this is not a food-borne disease. You do not get this disease through eating pork and therefore, there is no reason to be afraid of consuming port or pork products. And as long as pork is cooked the way we normally cook meat, there is no problem and no risk at all to getting this disease. From an animal health point of view, it is still a mild disease, swine influenza is very common in pigs and, of course, from a public health point of view it is important to understand how the disease is present in animals because we also need to recommend and take measures to prevent further human exposure to sick animals. Because there is of course a risk for those heavily involved, or in close contact, with sick animals to get infected. It happens as with other diseases and it has happened in the past with classical swine influenza where on certain occasions, in particular workers on farms who are heavily exposed to these animals have been infected this way. This could, of course, happen here so we have to take measures to avoid unnecessary exposure of humans to sick animals.

**André Picard, Canada:** Thank you. I would like to ask you more detail about this swine flu infections in Canada. We know the person is better, the pigs are better, but is there not a risk in this mixing of pig and person influenza? Doesn't it risk getting worse and going back into the population as a more severe and dangerous strain?

**Dr Ben Embarek:** The way I understood the question, you are asking if there is an increased risk of having the virus circulating back and forth between humans and animals? The virus that has been isolated from swine in this event yesterday, does not seem to be different from the one circulating among humans. There is no sign that it has changed at all. But this could of course happen like with any other influenza virus. As you know they change all the time and it could really be the case that, by moving in the swine population, it would again change. But we cannot anticipate this and it is therefore important to continue to monitor the situation, study the different viruses we isolate, and increase our surveillance both in humans and in animals in order to better follow any possible change in the future.

**Gregory Hartl:** Before we move to the next question, I would just like to add and to emphasize that as an influenza virus changes, it can become both more or less severe, or stay the same. So it could happen with further changes that the virus becomes less severe. We don't know at this point.

**Steve Connor, The Independent:** Yes, it's about the potential movement from Phase 5 to Phase 6. As far as I understand, for Phase 6 we need sustained transmission in at least two WHO Regions. We have a sustained transmission in the Americas and at the current rate at which we are seeing the increase of transmission, when do you think we are likely to go to Phase 6?

**Gregory Hartl:** That is not very easy to predict because transmission of influenza virus or any virus for that matter does not necessarily always move with the same speed. There could be a hiatus in its spread, especially we have not seen any confirmed instances of sustained human transmission in communities outside of the Americas. We don't know when that will happen. Certainly we will remain on alert in case that happens. But it would not be prudent to try to make a prediction in that regard. We would almost inevitably have to say we were wrong next week.

**Saki Ouchi, Japanese broadcast:** Are there any plans for the Emergency Committee to be held in the near future? And when Dr Ben Embarek mentioned the need of taking the necessary measures, are you indicating maybe slaughtering the swine at any point? There have been cases of slaughtering swine in Egypt because of maybe unscientific rumours. What would you say to those in less developed countries who may not be able to get information as rapidly as the more developed countries?

**Dr Ben Embarek:** There is at present no particular recommendation to cull any pigs anywhere in the world. Normally, FAO (Food and Agriculture Organization of the United Nations) and OIE (World Organisation for Animal Health) are our two sister organizations in charge of recommending specific control measures to deal with diseases in the animal population. From a public health point of view, and looking back in the past at other new diseases appearing where animal and humans were infected, there are always different ways of dealing with these diseases. You can either start vaccinating the animals in a particular area, you can also decide to cull the affected herds in an attempt to limit the spread of the disease, or you can increase biosecurity measures to make sure that nothing comes in or out of that particular farm. These are the main measures that are normally being used to deal with these types of new diseases. And we saw that these three types of measures were used and are being used, for example, in dealing with avian influenza outbreaks in poultry in many parts of the world over the past four or five years. Some have worked in some areas, and some others have worked in other areas, some countries have taken a combination of these measures to deal with the disease, depending on national situations, national specific environment, national differences in terms of how you raise animals and how you interact between humans and animals. But in our particular case here, there is at present no recommendation for culling and I know that FAO and OIE are recommending increased biosecurity measures for the time being. But from a public health point of view we are also following the situation and we also have to better understand how the disease dynamic goes in the animal population to better assess how humans could be affected, or at risk for further transmission and whether there is a need for taking more drastic measures. There are also ongoing inoculation experiments, at least in two laboratories, where they are inoculating the virus in pigs to give us a better indication of how the disease affects pigs and that will help us design more appropriate, more specific control measures in order to protect human health.

**Gregory Hartl:** Regarding your other questions, no, there is no further meeting scheduled.

**Richard Knox, NPR**: Two things if I may. A little while ago on television Secretary Napolitano of our Homeland Security Agency said that she expects that there will be an elevation to level 6 and she said it could very well be this week. If possible, could you spell out what that would trigger when and if it happens? Secondly, would the Emergency Committee be reconvened before such a decision is taken? Secondly there have been a couple of confirmed reports in the past couple of days from Costa Rica and Colombia about cases in Central and South America. Could you sum up what you know about these cases and what you are doing to track southern hemisphere appearances of this virus?

**Gregory Hartl:** Now first of all for us going to Phase 6, if and when we do, implies that we would help our Member States, especially those Member States that are not as well off as others, to increase a range of activities in terms of clinical infection control and clinical treatment of cases, in terms of surveillance to try to pick up unusual disease events, in terms of diagnostics to be able to better and more quickly diagnose cases as they come. We would also be shipping materials and medicines such as oseltamivir. So there is a range of very specific things that we would do both ourselves and in support of national ministries of Health. We are of course aware of certainly the case in Costa Rica has been confirmed to us and we are actively following up reports and any other instances of other cases that we hear of in Latin America and elsewhere around the world.

**Jamil Chadai, Sao Paulo**. Could explain why is it that WHO insists that embargos on pork meat is not recommended and actually that trade can go on, and eating can go on, if you just said that you are actually studying the effects. How is it that you are 100 percent sure that it is not going to be a problem? Yesterday night we got a press release from WTO about this issue. How does WTO know whether pork is safe or not, and could you please explain to us if there will be a scientific meeting tomorrow. If that is true or not and if so, what will they deal with.

**Dr Ben Embarek:** First on the food safety part: influenza viruses have many features and some of them, in particular in relation to the way they transmit to humans or animals, change as we know very often. But, from all the studies that have been done with influenza viruses, whether it is avian influenza viruses, human viruses or swine viruses, they all seem to have more or less the same characteristics in terms of their heat resistance for example. And we know that they are not very resistant to heat, meaning as soon as you cook a product that may contain these viruses, they will get inactivated. So consuming fully cooked or well cooked products, whether we are talking about this virus in pork or avian influenza virus in chicken, there is no risk of getting infected that way. Where we are concerned is if the virus is present in the live animals, then the people who are handling these animals, we are talking about farm workers, about veterinarians, about slaughter house workers, those might be at a higher risk because they come in close contact with the animals, they come in close contact with the body fluids of the animals, and that is how you could get infected. We know that with other animal influenza viruses – again looking at avian influenza or other traditional swine influenza viruses – there has been instances where people have been infected through handling the live animal or slaughtering it but these are all the steps before preparing or before trading it or using it for food. So it is the early part of the food chain where you might have a risk of transmission with this close contact to body fluids. But at the other end, at the consumer end, we know that there is virtually no risk because you don't get in contact with these fluids, you get in contact with the meat, which is either free of the virus or the virus will get inactivated during any processing you undertake with the product. So from a consumer point of view, there is absolutely no risk of consuming cooked products. And therefore we say that trading meat for example, whether processed or raw or frozen meat, should not be restricted because there is virtually no risk of transmission that way. We have to send these different messages, that you might have a risk with the live animals, or when slaughtering them, but on the other side, as soon as you are dealing with the final product, there is no big risk. It was easier somehow with bird flu and the chicken because there it was clear that when you buy a chicken wrapped-up in the supermarket, it is easy to cook and you don't get exposed to anything. But if you are sitting in a farm and do your own home slaughtering somewhere in rural Asia, you are of course exposed to a totally different environment. And this is a similar situation that we might see here.

**Gregory Hartl:** Scientific Committee will be looking at various elements of what we know and don't know about the A(H1N1) virus. If we can make any appreciation of incubation periods, of severity or not, or mildness of the virus, which groups might be most vulnerable, etc. That will be what it's looking at.

**Mark Anderson, The Times:** Two questions: first of all, there are reports coming out now, at this moment really, from the Mexican Health Minister, saying that the epidemic is in the phase of decline, the national peak was between 23 April and 28 April. Do you have anything to say to that? And secondly, how concerned are you about the ongoing situation in Spain, where the number of confirmed cases has been doubled to 40 today? I understand most of those are Mexican contacts, that is, does the presence of so many cases in one country enhance the prospect of human-to-human transmission?

**Gregory Hartl:** That might be certainly what the current epidemiology is showing. I also would like to remind people that in 1918, the Spanish flu showed a surge in the spring, and then disappeared in the summer months, only to return in the autumn of 1918 with a vengeance, and we know that that killed eventually 40 to 50 million people. So, I think while tracing these kind of curves of activity – increase and decrease in activity – we cannot lower our guard. There is a high possibility that this virus will come back, especially in colder periods. Mexico is in the northern hemisphere, we are entering in the summer months where normally the influenza activity is low, so I think we would want to wait a while before making a definitive decision. But certainly maybe this current round of activity has peaked, but we are really normally ten days into this outbreak, so we must wait and see. And in Spain, we have the reports of increasing numbers of cases in Spain, we are watching this closely. For the moment, however, they appear to be following the same pattern, largely being imported cases from Mexico, and before we would consider moving to Phase 6, we would really have to see a sustained community-level transmission within the country, outside of the Americas.

**Michelle, ABC:** The CDC has said that the origin of the H1N1 outbreaks was in Mexico. Is that still the thinking? Are you still looking, where are you looking, and what are your best working theories?

**Gregory Hartl:** We have heard that, but actually that is not really a priority for us for the moment. For us the priority is what is happening at this moment and what we can try to do to stop the virus from spreading further. So we are looking forward and I think it is an interesting question and hopefully someone will be able to look at it in more detail later, but for the moment what we need to understand is the current behaviour of the virus. How had it spread? To which age groups? To which groups in the community? And is it predominantly severe or mild? Over how many generations does it spread? Questions like that, that is going to help us the most to respond to and to control this event.

**John Acostas:** I was wondering, if you could elaborate on the swine fever that has been detected. If there is a risk where you have farms where pigs coexist in a farm yard with chickens, especially in Asia, is there a risk if there is an avian H5N1 outbreak with swine, of the two mixing into a cocktail?

**Dr Ben Embarek:** Yes that is of course the concern, if it happens, but we have no way of knowing if and when this could happen. But again it is one of the reasons why it is important to monitor the situation in animals actively and to ensure that the disease, if present in animals, does not spread geographically, and precisely to other places where it could pick up more strength from other viruses.

**John Cohen, Science Magazine:** When was WHO notified about the Canadian herd, and given the reports of more than 200 of the pigs infected and of possible transmission back to another farm worker, does this tell us anything in terms of a natural experiment about containment of this virus?

**Dr Ben Embarek:** Yes, apparently about 220 animals showed symptoms out of the herd of 2200, so approximately 10% of the herd got infected. This tells us that also for the animal population, it doesn't seem to be a very serious disease and it is apparently from what we know something that is not surprising, and could be expected from a virus like this. We have no information about other people who might have been infected following that event, so we will have to wait and see what comes out of the current investigation. We know that the farm has been put under quarantine, and no infected animals have left the premises, and these are the measures that should be taken in such an event.

**Brad Clapper, AP:** When there have been questions about food safety, you have said on different occasions that as long as the ham is cooked in the normal way we cook it, it's okay. What about for ham that is not cooked, knowing that people eat ham in different ways, including raw. Do they now have to fry up prosciutto, jambon cru, all other forms of pork in order to be safe? This has never been mentioned in anyway by you guys?

**Dr Ben Embarek:** No, there is no reason to start destroying these wonderful traditional cured products. You should not forget that to produce a ham it takes a long time where the product is maturing, and this process is also believed to inactivate any virus that might have been on the raw material in the first place. We know that influenza viruses would not survive very long on surfaces or on meat products, for example, so the duration that these products undergo during processing would, even if it the process itself did not inactivate the virus, just the time would be enough to inactivate viruses. So you can continue to safely eat your prosciutto.

**Denise Grady, The New York Times:** I would like to repeat one that John Cohen asked that did not get answered, and that was when did WHO find out about this herd in Alberta.

And then I would also like to ask if it is necessary, based on this, to have more surveillance of animals, and what exactly does that mean? There are an awful lot of hog farms everywhere.

**Dr Ben Embarek:** We learned about this last night Geneva time, and I believe that it was the time when it was announced in Canada. As I said, the farm has been put under quarantine, there is no indication that other farms in the vicinity or elsewhere in Canada should be affected. We also understand that the Canadian inspection services and also their counterparts in the US and in Mexico are of course increasing their surveillance activities, and so far no other pig populations have been detected or reported to be affected. But of course, since this has happened once, it could also happen again elsewhere, and therefore it is also important to reiterate to those humans affected, that apart from taking care of not infecting other humans, they should also stay away from pig farms and in particular from close activities involving pigs.

**Izumi Oki, NHK, Japanese Television:** Two questions: are you saying that as WHO you recommend countries to step up surveillance on swine population? Second question: for people who would be exposed to infected animals, slaughtering pigs or so, what should they do, what do you recommend?

**Dr Ben Embarek:** To the first question: WHO does not normally recommend animal health authorities to take actions, but we understand from what FAO and OIE have been saying to the animal health authorities is that they are increasing their surveillance of the animal populations, in particular in the countries affected. This is something that is necessary for a better understanding to what extent animals are infected, and if they are, to both protect humans and prevent further spread among the pig population. As for those persons who are involved in close contact with live animals on pig farms, in particular farm workers, slaughter house workers, and all those involved in these activities, they should of course – in the case there is an outbreak of the disease in the farm among the swine population – they have of course to protect themselves, avoid unnecessary contact with the animals, avoid contact with body fluids from these animals that are typically the way you would get the disease transmitted, and in some cases, but we don't know yet, in some cases they might need to wear particular protective equipment. But at least, it is also important to re-emphasize that these farms should be quarantined immediately, the herd should not be allowed to move around, in particular not to spread the disease further among other farms and other pig populations. Therefore it is very important that we understand exactly how the disease appears and spreads in an animal, so we can better advise farmers and veterinary authorities on what they should be looking for, and also so they are capable of identifying the disease and take measures immediately as soon as the disease appears in an animal population.

.

# Transcript of virtual press conference with Gregory Hartl, WHO Spokesperson for Epidemic and Pandemic Diseases, and Dr Keiji Fukuda, Assistant Director-General ad. Interim for Health Security and Environment, World Health Organization

**4 May 2009**

**Gregory Hartl:** We would like to welcome today Dr Keiji Fukuda, WHO Assistant Director-General for Health Security and Environment. Thank you very much, and now over to Dr Fukuda.

**Dr Fukuda:** What I am going to do today is just cover some general points. I think that there have been a number of questions which have come up and I am happy to answer those. But in keeping with the way we have been doing these press briefings, what I will first do is provide an update on the current situation, the figures, go into a little bit about an assessment of where we are, and then I will be very happy to take any questions.

As you know, we have been really stressing the fact that we shouldn't focus too much on the figures because they are pretty fluid and they change fairly often. To give an example, the Director-General addressed the General Assembly of the United Nations just a little while ago and at the time that she gave her talk, the figures of numbers of cases was 1003, but an hour later, as we get updated figures coming in from countries, the numbers are a little bit different. At the current point now, from the figures that we received just a little while ago officially, we are dealing with 1025 laboratory cases –similar but different. And these include 26 deaths and the cases have been reported from 20 countries and that's as of a little while ago this afternoon.

In terms of the overall situation in the epidemiology, the largest number of cases have still been reported from North America. The greatest number of cases have been reported from Mexico, the United States and from Canada. But we have continued to see a number of infections related to travel in a number of different countries, so these have included reports of cases in Asia, in Europe and in Latin America. We see a little bit of movement of the virus going south. At this point, these cases in other countries including Spain and in UK, which have had a number of cases reported remain travel-related cases. We do not have any evidence that the virus has taken hold and has led to community-level transmission in any other countries right now. So our overall assessment is that the situation continues to evolve as we have been stressing from the beginning, and in keeping again in the messages from many speakers, we are not quite certain how this is going to evolve. There is always uncertainty about the evolution of a new disease as it spreads worldwide. I do want to emphasize that at this point in history, this is the best surveillance we have ever had. We are really monitoring and able to see a situation unfold in a way we have never been able to do in history before. So again I think that people are watching perhaps the virus move out and seed itself in different parts of the world. But this is a new phenomenon, this would not have been possible 20 or 30 years ago.

Now, in this situation, it is critical that we continue to maintain and strengthen our alertness and surveillance. We have concerns about the infection travelling to the southern hemisphere because that part of the world will be heading into the winter months and the winter months are when influenza viruses usually thrive, and so you typically see epidemics and outbreaks of influenza occur during those colder months. But, I think you can see from right now, that this virus continues to move to a variety of countries in the northern hemisphere. So it is not that surveillance has to be strong just in the southern hemisphere, it really needs to be strong everywhere. Right now we really don't know how this will go, what other countries it may move to in the northern hemisphere and in the tropics. We are very mindful however, that we are heading into the winter in the southern hemisphere.

The issue which many people are asking about – rightly so – is about the spectrum of illness. What do we know at this point? To summarize from the information that has come in from all of the countries from the cases we can see a spectrum of illness going from very mild cases where people develop some fever, some symptoms but don't require hospitalization, to cases that end in fatalities. As I mentioned earlier, we now know that 26 people have died from this infection.

There also have been some important observations that have to be verified but they are important observations. So from the investigators in Mexico, for example, we know that severe pneumonia and death can occur in young and healthy people. This is a very important observation we have to follow up on and keep monitoring. Another kind of observation is that ,based on the available cases, we have seen that diarrhoea is reported more often than we typically see with influenza. So there may be 40–50 percent of cases which develop diarrhoea which, again, is more than we see with typical influenza.

At that point, I think it is hard to say much more about the clinical spectrum of illness. We do expect information to continue to be collected. The investigators are very mindful that this is one of the critical aspects that we all want to know about and so I expect more information to come in over days and weeks.

Another question related to the illness is the incubation period. To put this in perspective with regular influenza, we typically see that the incubation period for influenza viruses is probably up to about 5 days – that would be a good range of incubation periods for regular influenza. With this virus, based on the current investigations, there is some uncertainty as to whether the incubation period may be up to a few days longer. So, there are questions about whether the incubation period may be 6, 7 or 8 days. Again I think the investigators will be working hard to refine those estimates. But that's the current question about the incubation period.

If we ask ourselves what are the main questions about the disease that we would all like to know about, I think the most important one is how often does it lead to severe disease. If you infect a large number of people, will you expect to see a small percentage develop disease that needs to be hospitalized or will we expect to see a larger number of deaths. I think these are the questions that we are trying to understand as quickly as possible. Again I mentioned that diarrhoea may be a more prominent feature of this illness than with usual influenza. Are there other symptoms? Are there other unusual findings? Again this is an important question.

The third area of questions is what age groups are most heavily affected. In past pandemics we have seen that all age groups are affected, but sometimes young and healthy people can be disproportionately affected compared to what they normally would be from regular influenza.

So these are the kinds of questions that the investigators are looking at right now and trying to figure out.

A third point I want to cover is the pandemic phase, because there have been many questions about this. How would we go to Phase 6, what does it mean exactly. So in terms of what we are looking for, the difference between going from being in Phase 5 which is where we are seeing sustained community activity in at least two countries in one region in North America, we are now looking for whether there is evidence of sustained community transmission in a country in another region. So it could be Europe, it could be Asia, it could be in Africa, it could be in South America, but we are looking for the evidence of that and that is why we are monitoring the cases so carefully to see whether there is any evidence that there is a pattern different than the travel-related cases.

There is some confusion about whether going to Phase 6 says anything about the severity of disease. These are separate issues and I hope everyone is very clear about it and if you are not, please ask me questions. Phase 6 means that we are seeing continued spread of the virus to countries outside of one region, and if we are seeing community outbreaks occur in multiple regions of the world, it really tells us that the virus has established itself, and that we can expect to see disease in most countries of the world. But that is different from the severity of a pandemic.

The severity of a pandemic has to do with when people get infected, how often are they going to develop really severe disease. Will we see younger people develop serious disease more often than usual, will there be anything unusual about pregnant women, will there be anything unusual about children? These are the kinds of things that we would be looking at in order to determine severity. So there are two separate things. I hope this is clear and please ask me if it is not.

This is the last point I will make – just to summarize the kinds of actions we are taking at WHO and I hope it gives you an idea on what we are focussing on. The first thing is that we continue to stress with countries and continue ourselves to be very alert as to what the disease activity is. We are stressing monitoring as a very critical first activity, and as we keep saying the situation is evolving. The only way we are going to know how does it evolve and are there any important changes is by ongoing surveillance around the world and the participation of all countries. So this is activity number 1. At the same time however countries, communities, institutions, have to deal with the situation at hand. They want guidance, they need guidance. So there are a variety of questions that people have. How do we take care of sick people, what kind of control measures might be instituted, what kind of surveillance is recommended or what case definitions can be used and so there are a lot of questions like that. One of the things we have been working on from the beginning is to provide that kind of guidance. And again, it is something that you have to work pretty hard at in the beginning when you are dealing with a new disease, recognizing that there are often things which are unknown.

The third area which we are focussing pretty heavily on, is what is the science. And when we are dealing with a new disease we can look at how things develop, we can describe what is going on, but we really want to understand why, because it is the "why" which is going to give us a handle on how do we handle this better, how do we treat it in a really scientific way but science does not come overnight. So there again, a lot of groups, a lot of people asking a number of questions about the disease, about the epidemiology and it something that we will continue to facilitate. To give you an example, last week we held a global science meeting focussing on most of the areas: the epidemiology, the viruses, the clinical features. Tomorrow, we will be hosting a second global virtual conference to focus more on the clinical aspects, and to try to get at the question of what is know about the severity. These are one of the examples of how WHO will try to bring together the science as quickly as possible.

A fourth area that is really in keeping with WHO's core mission and where a lot of the heavy lifting has to be done is how do we shore up the capacities of countries to deal with the situation, being mindful that the resources and capacities of countries differ out there. This is one of the core areas where WHO typically spends a lot of its efforts, trying to identify from country to country, what are the needs there, and then to bring together the international community. So this may mean working with donors, it means working with technical partners. It means working with all of those different entities out there that can provide help – UN organization sisters and so on. This is another large area of work going on simultaneously. All of these things are going on at the same time. It is not like you deal with one of them first, then move on to the other, you just add on to them and continue. That is a broad overview of where we are right now, so why don't we throw it open for questions.

**Saki, Japan:** Could you shed a little more light on the Scientific meeting tomorrow? How many scientists are participating? What is the role of Dr Chan? The 29th of April, if my memory serves me right, is the last time we had the science meeting, after that there was the 10 o'clock press conference with Dr Chan, which raised the level from four to five, does this science meeting suggest anything? Thank you.

**Dr Fukuda:** Let me answer the second last question first. No there is nothing planned. This meeting is planned independent of anything else. One of the things that we are trying to do is to identify what are the most pressing scientific issues, and then to try to address them as quickly as we can. I think that right now, the severity of illness – the clinical features of illnesses – is one of the most important questions, and so in the future we will identify other questions and try to address them. These kinds of meetings are different from the traditional scientific meetings, where you bring a lot of people in a presentation. Because we are dealing with a situation that we consider serious and urgent, what we are doing is sending a call out plus asking investigators that we know are looking at this, to join the conference, which will be done virtually, and then what we do is to ask the investigators who have been seeing the cases to present the information: go over what they have found, and then allow doctors, physicians, scientists from other parts of the world, to ask questions, and this fosters a dialogue. This is much quicker than going through publications. It is much quicker than any other way. It is a very direct discussion literally between people in different parts of the world able to ask questions. So, in this kind of meeting, Dr Chan is really the person championing these sorts of meeting, pushing for these meetings, but she will not participate in it directly.

**Helen Brownswell:** I was wondering if you could clarify something about what would trigger Phase 6. If this virus behaves in the way seasonal flu viruses do, and activity in the northern hemisphere starts to subside in the coming weeks, but we see it peak up in the southern hemisphere, that would obviously be another region, but would that, if it not concurrent, if it is not sort of spreading in the community in the northern hemisphere, it is in the southern hemisphere, would that be Phase 6 or would you need it in two regions of the southern hemisphere to qualify?

**Dr Fukuda:** To go back to what Phase 6 mean. The idea of Phase 6 was to capture how was this virus spreading and how far out had it spread? Typically with influenza we know that there can be more activity in the winter months in one hemisphere, than the other. We are not focused on whether we are seeing activities at the same time, we are really trying to get a handle on how far has it spread out and has it really established itself in different parts of the world. So I think that concurrency of activity in one part of the world or another is not so important as it is as showing that the virus has really established itself now in the southern hemisphere as well as countries in the northern hemisphere. I hope that answers.

De**borah B, from Global:** Based on these 26 deaths, what can you tell about what kind of persons could be more susceptible to develop a severe disease. Did these people who died were mostly young, healthy? Did they all develop, had diarrhoea or these kinds of things.Do you have any elements at this point?

**Dr Fukuda:** Right now I have not seen a detailed analysis of the people who died, and so there maybe people or investigators who know much more about the specific features of the people who have died. I think that right now we do know that some of the people who have died have been young and healthy. We also know that some of the people who have died have also had other illnesses going along. Typically influenza can more severely impact people who have other illnesses too. But I cannot tell you much more than that, and I cannot give you details at this point. But I think that in future, hopefully in the not just the future, we will see a much clearer analysis of whether there is anything that we can say pre-disposes the people having severe illness from – or severe outcomes – from this infection. So I cannot tell any more than that right now.

**Bougaren, Reforma Newspaper, Mexico:** I have two questions if I may. As you know Dr Fukuda in Hong Kong, around 300 guests are in a hotel in quarantine until May, after a Mexican hotel girl was found with being infected by the virus, between these 300 guests are 21 Mexicans. What do you think of this measure? Does WHO support this kind of measure against this virus? And the second question is that, the WHO knew for the first time about these initial cases in Mexico influenza back in the 10th of April and following day informed the Mexican authorities. For the second time WHO alerted the Mexican authorities on 17th of April. Could the Mexican authorities have reacted against this virus before 20th April when there was this teleconference? What could the Mexican authorities do in this period?

**Dr Fukuda:** The question is about quarantine. Let me talk a little bit about disease control to put this in perspective. When you are dealing with infectious diseases, quarantine has been a long established principle and so what quarantine means, is that when somebody has been in contact with people who are infective, or who are ill, and what you may ask them to do is to be in a place where you can observe whether they develop symptoms and so on. This is what quarantine is. It is different than isolation. Isolation is when somebody is sick and you put them to the side a little bit so that they reduce the chances of infecting others. I do not want to comment on the specific disease control actions of different countries. I do want to point out that quarantine, in specific situations, can be applied and it is a quite reasonable action to take in specific situations. There are different times when it would be reasonable and other are times when it would not be reasonable. In the guidelines pointed out, or developed by the World Health Organization in terms of pandemic Phases and preparedness, if you go to that document again you will see that there are considerations of when to apply quarantine, when to apply isolation as considerations. But as we have mentioned over and over again, the situations differ and countries approaches to diseases control measures are choices. There is no set recipe of how you approach disease control and so this will differ to some extent from country to country. So I will leave it at that.

**Frank, AP:** I would like to pick up on that issue of the quarantine because it has been so much in the news over the weekend. Specificly the China has been taking some measures and not just in Hong Kong, but throughout the whole country, so they restrict the movements of Mexican nationals. Can you comment at all on that? And in a sort of related question, if a country that has taken drastic measures claims, like Mexico for example, that the infections are dying down, is it fair from your point of view to actually make that claim or is any country ever going to be safe if there is still a virus going around in the rest of the world. Could they come back?

**Dr Fukuda:** I really do not want to comment on specific actions taken by specific countries. You know there are instances where quarantine makes sense. For example we often have cases which occur in families and so we know that other people who are not sick have been potentially exposed and that it is good for those people to be on the watch out for whether they develop symptoms and so on, and that you know there are general times when quarantine makes sense. With the WHO's guidance on quarantine and isolation, there is emphasis on them sometimes in the earlier phases as we get later on into Phase 6 then these sorts of measures will become less useful because there will be just more infections around and you cannot quarantine everybody in the world. So there are selective measures that you take in specific situations. Again I will leave it at that.

In terms of your question about the activity going down in Mexico, I think that one of the confusions about this phenomenon that we are looking at is, that people often imagine that pandemic disease spreads everywhere in the world at the same time. That there may be a simultaneous way of which just it sweeps around the world at the same time. But the way these things occur is that we expect that you will have peaks of activities in some places and then you will have valleys of activities in other places, you will have lulls in some places, you know the hemisphere, which is in the summer months you would expect activity levels perhaps to be lower than activity levels in the hemisphere that is having winter months. And so it is a mixed picture. This is what we have seen in other pandemics. This is what we see with seasonal epidemics, and this is probably what we would see in this situation, if it does continue to spread and become a pandemic. So let me leave it at that.

**John:** I was wondering on the 26 deaths, if you have any information from the Member States if some of the patients that died were on antivirals or other medication. And my second follow-up question is, the 72 countries where you are going to provide the antivirals, how many of these countries have any pandemic strategy in place, or are they the countries where the strategies are a bit weak?

**Dr Fukuda:** I do not have precise numbers, I do know of the people who have had serious illness, this includes people who have survived but have had serious pneumonia, and then probably some of the people who have died, were given antivirals. But I think in many of these instances, the antivirals were given several days into the course of illness. So some of the information I have heard for example is some of the people were treated at day five or six. Typically, with the antiviral drugs you want to give them within the first two days of illness to give yourself the best chance that they will have an effect. So if you are a physician you are going to treat them with everything you can, whenever you can, to try to see what you can do, but it is probably not a fair task to tell us about the effectiveness of these drugs.

In terms of the question about what do we know about the effectiveness of these drugs, the viruses are sensitive to oseltamivir at this time of year, we know that these drugs work against the wide range of influenza A viruses, and so we expected it would act against this virus too. But, effectiveness means that you have good studies showing that if you give it, you reduce illness by a certain percentage and so this again requires that fairly rigorous studies are set up and done, and so those are not set up and done for this particular virus.

In terms of the countries that are being provided with antiviral drugs, these are generally the countries that have the least resources. Many of these countries have strategies, and have plans in place, but they do not have the capacities to carry out many of the things, and so for example, if in your plans you put antivirals there as part of your overall approach to a new influenza infection, you still have to have the antivirals available to carry out those plans, and so that is one the things that we are trying to help with.

**Question:** First, just a clarification. We have asked for the list of the 72 countries that received – if there is a list of the 72 countries and if you could provide that to us it would be very interesting, especially to know who gets what and how much. This would be one request and secondly you mention again the virus going south. When do you expect – I know it's difficult to predict – but it seems that this virus peaked, at least in the northern hemisphere at the end of the winter. We are still in the southern hemisphere in autumn. Do you think it will take a couple of months still or can it actually be activated immediately?

**Dr Fukuda:** I don't have the list of 72 countries right here but we will try to facilitate. In terms of the timing of movement to the south, if you think back just to last week we went from Phase 3, to Phase 4 to Phase 5 relatively quickly and then right now we are not certain when we will go to Phase 6 and I think it points out some of the uncertainties about how these things unfold. There is no timetable for how viruses like this spread out. I don't know when we might see travel of this virus to the southern hemisphere and outbreaks there, or whether we will see them. Again, as we have always discussed we can't predict the future but if it does move to the southern hemisphere we could see outbreaks within the next several days, we could see outbreaks within the next several weeks, or maybe longer than that. It is simply very hard to predict on these things and we are careful to try not to create any false expectations.

**David Brown, the Washington Post:** It seems to me that it is really important to know about what has been happening in Mexico in recent months and not just for historical purposes. I am wondering Dr Fukuda if you know, or anyone knows, whether this diarrhoeal disease that may in fact have been influenza, how far back that goes; has there been an outbreak of diarrhoeal disease for months? As a related question the travel-related cases that are in Europe and also in the United States, were they all to places that had known outbreaks of some unusual respiratory disease, i.e. Vera Cruz and these other places, or did those travellers go to parts of Mexico where there had not been observed respiratory illness which would suggest that it was all over Mexico months ago?

**Dr Fukuda:** I think that the epidemiological picture of this virus in Mexico will take a considerable amount of time to see clearly. I think if we go back to how events unfolded, one of the things that is important to understand is that it was back in March that there were influenza-like illness cases which were going down and the signal which really caught the eye of the Mexican health authorities was the increase in severe pneumonia cases and particularly among young people. There was not a signal so far as I know of an increase in diarrhoeal cases preceding this and I want to point out that we are looking at diarrhoea in the context of a respiratory illness. When you look at what kind of illness are these people developing, it is not just diarrhoea by itself without the other symptoms, it is diarrhoea within the overall picture of respiratory illness.

In terms of travel to known areas, again I do not know the full travel history of many of the people who have travelled. I think that there were people who had travelled to parts of Mexico before it was known that they had infection in that area but again I don't have a detailed accounting of all of the many travellers.

**Hedayat, Abdel Nabi Kuwait Agency:** Could you please brief us on the situation in Alberta, Canada, that some people spoke about yesterday. Is it the same pace of infection in the pigs like human infection. Like each day now we are one third up in human infections; yesterday it was reported 220 out of 2300 swine. What is the situation today, have other farms been infected, the people surrounding those farms. Could you elaborate on that?

**Dr Fukuda:** I will discuss it to the extent I know any details about that particular situation. In Alberta it was reported that there were signs of infection of this particular virus in a herd of pigs there. To put this in context, influenza is a virus which commonly infects pigs. There are many different swine influenza viruses and these have been know to be infectious for pigs for many, many decades. So it is not new that influenza infects pigs. There is no similar pandemic system for pigs. We just know that in different herds in Europe or in Asia or in North America that they may be infected with one influenza virus or another influenza virus. I don't know of any other outbreaks occurring in pigs at this time. I think this is a finding that is interesting and it is important to investigate it further to see whether this virus is going to be found in other herds of pigs but I want to stress the big picture here which is that the infections that we are seeing in people are not coming from them having contact with pigs. This is really different then from the H5 situation where people were getting infected by having contact with poultry. This is really a situation where people are getting infected from other people who are infected. So really, a different situation.

**Joanna Smith, the Toronto Star:** Just going back to the Alberta farm, what are your recommendations now for pork producers around the world and are you recommending that countries ban imports or exports. What should people be looking out for?

**Dr Fukuda:** Let me answer this in two different steps. The recommendations for how to handle pig herds and poultry are really the really the area of FAO and OIE. WHO does not make recommendations on how to take care of animals. What we do focus on is what steps might be taken to protect people from getting infected from animals – zoonotic infections – and also we concentrate very much on the safety of food. In this instance we are very clear that pork and pork products when they are handled right and when they are cooked properly do not pose a risk of infection to people. That is very clear. Here again we are dealing with a situation where the people who are getting infected are not getting infected from pigs. Having said that, of course, we always want to be careful and make sure that there is no risk so this is something that we would continue to look at as to whether pigs may pose a risk to some people but this is really not how people are getting infected and this is really important to understand and be very clear on. The pigs are not the danger to people right now, the danger is from people transmitting infection to other people and this is what we hope to control as much as possible and reduce the dangers.

**Isowi:** I would like to know about oseltamivir. Everybody knows that if you use huge quantity of same antiviral there will be resistance. Currently, how many people are treated by Tamiflu and are you concerned by resistance to oseltamivir.

**Dr Fukuda:** With any drug that is used to treat a pathogen whether we are talking about bacteria or virus, then resistance to that drug is always a concern. Of course we are concerned about whether this virus could develop resistance to oseltamivir because right now it is sensitive. Having said that oseltamivir can be a very useful intervention for treating people who are sick and so I think there is no reason to hold back from using it because we are concerned about resistance. In this situation, what we do is try to monitor the viruses which are isolated, try to do the appropriate studies as quickly as possible to identify whether we see any emergence of resistance. At this time, we do not see any resistance to this drug in this group of viruses but we will keep watching it closely.

**Lara R, Quattori, Italy:** I would like to have more figures on the number of deaths that are still being investigated and the ones that resulted negative. So the whole picture for the data – the positive, the negative, and the ones still to analyse – and the same with the number of cases of suspected flu. How many are still to be investigated?

**Dr Fukuda:** This is a figure that we do not track very carefully. The suspected cases – all national authorities investigate disease cases – and then there are ones that they have confirmed cases by doing the laboratory testing and then they have other cases that they are looking at. But it is not something that we ask the countries to report to us, it is not something that we try to track because the laboratory-confirmed cases is really the clearest way to monitor the spread of the virus around the world. Then we are not dealing with ambiguities, I simply don't have those figures, I can't tell you how many investigated cases there are right now.

# Transcript of virtual press conference with
# Gregory Hartl, WHO Spokesperson for Epidemic and Pandemic Diseases,
# and Dr Keiji Fukuda, Assistant Director-General ad Interim
# for Health Security and Environment,
# World Health Organization

**5 May 2009**

**Gregory Hartl:** With us today is Dr Keiji Fukuda, the Assistant Director-General for Health Security and Environment at WHO, who will give us an update first.

**Dr Fukuda:** Welcome everybody and thanks for coming again. Actually I was literally on the call – we were having the clinical call that we were talking about yesterday to go over illness and so I don't have any prepared notes for talking today. I was trying to understand what I scribbled down during the talk so literally I will be putting together what we just talked about in the past few hours and to try to make it understandable, both for myself and hopefully for the rest of you.

Just to give a quick assessment of the situation, we continue to see an increase in cases being reported by countries. The numbers that we had as of 2 o'clock this afternoon – but I expect these numbers to change and they will be updated in a few hours – but as of 2 o'clock this afternoon we had 1490 laboratory cases, and 30 deaths. Again the deaths occurring primarily in Mexico with the one other death reported in the United States, the previously reported child. This represents an increase of 405 cases and 4 deaths since yesterday at 18:00. I expect those numbers to increase again later on today or to be updated later today, so I wouldn't be too focussed on the numbers, but just to illustrate again how this situation continues to evolve and how we continue to follow.

Yesterday, one of the things that I said that we would be doing today is to have our second science meeting, which we did, and that was started at 3 o'clock this afternoon. When I came over here that was still going on. It is a virtual conference and so I don't have any prepared notes from that and I was trying to collect my thoughts about what was being said. Similar to the first conference call, this was a call in which the investigators of a number of different countries were reporting what they were seeing and their understanding of the information that they have at this time now, and again we focussed the discussions primarily on clinical illness. We talked a little bit about viruses and those sorts of things but we are really focussing more on the clinical illness.

One thing I think which is true is that so far, among the cases being seen everywhere, including the countries with the large number of cases, is that the people being infected continue to be relatively younger people. In general we are seeing the infections occurring in people who are younger than 60 in almost all countries. There are some exceptions but in general the bulk of infections are occurring in younger people and when the investigators are looking at the average age of people getting infected, this is often in the age range of people around the 20s – mid-20s – a little above or a little below. I want to point out something about this. One of the things about many of the infections are that they are being reported in people who have been travelling and so one of the questions which came up is whether most of the people travelling right now going to these countries tend to be younger people. So is this really a reflection of the disease or is this a reflection of some of the ways that people are getting infected? So does this naturally reflect a younger age group. One of the alternate possibilities of course is that it is an infection that is primarily going to younger people because there may be something about older people which is preventing them from being infected. And again, with influenza oftentimes we see the infections go to younger people first and then go to older people later. It may be that we are seeing something like that. It also may be that there is something about older people, that they may have some level of protection that younger people do not, that may also be contributing to the reason why we are seeing infections in younger people. I will try to point out the different kinds of possibilities for what we are observing and these are the kinds of questions again that investigators will look at over time to try to tease through.

One of the second things which is pretty clear from all of the countries, is that in general males and females are getting infected at about the same rate. This is not so surprising for influenza. This is what we normally see with influenza but again the data we are seeing now confirms that – or suggests that.

Over the past couple of days we have talked about incubation period – this has come up actually ever since we first saw the disease and if you remember earlier on, some of the estimates were for up to a week or perhaps a couple of days longer, which in an earlier briefing I said was a little bit long for influenza. The more recent estimates are that the incubation period is somewhere from about one day to a week, or one day to five days in general, which is a little bit keeping in closer – or a little bit closer to what we expect for influenza viruses. Again, these estimates will continue to be refined. This is the newer information, so the incubation period being a little bit closer to what we normally see with influenza.

In terms of the illness itself, in the people who are developing generally milder illness, this is similar to the kinds of influenza-like illnesses that we see, so this is typically people developing fever, cough, body aches, headaches, and this is generally in keeping with what the milder spectrum of illness is. It is clear that we are seeing severe illness in at least a couple of countries. For example, in Mexico, as you know, we have been talking about how there have been a number of pneumonia cases and people requiring hospitalizations as well as fatalities. In the United States there are also hospitalizations that have occurred and the essential reasons for the hospitalization have generally been that people have developed severe respiratory illness – either pneumonia or some of these people requiring ventilation. Again the outstanding question – which is not clear yet – is how often is this occurring. But it clearly is occurring not just in Mexico but we now have some people that we know have developed similar illness in the United States. But again the big question is does this occur fairly infrequently or does this occur frequently. This is the kind of information that the investigators will look at more.

There were questions about whether we see infections in health-care workers and in general there have been a few health-care workers infected but it is not certain that they got infected in a health-care setting. This has not been something that has been transmitted to a lot of health-care workers.

In terms of the virus itself, there was some discussion about this and particularly whether there is any sense that the viruses being picked up in different places are the same or different, and again the information as it has been over the past week, is that the viruses look pretty similar that are being identified in different locations.

We still see that the virus is sensitive to the antiviral oseltamivir and the antiviral zanamivir – these are neuraminidase inhibitors – this is one class of antiviral drugs and the viruses continue to show resistance to the other class – amantadine and rimantadine – so no change in those sorts of features. Let me stop there. It's a fairly short summary because I have not put together notes on everything and let's throw it open for questions.

**Caroline Alfonso, Global Mail of Toronto, Canada:** I actually have two questions. Would you [unintelligible] China has moved to quarantine people. Do you feel that it is a useful measure. And my second question is there are a number of reports of community transmission in Europe and I am wondering if the WHO has confirmed any of these and whether it will trigger Phase 6?

**Dr Fukuda:** Let me address both of these questions. We have talked about disease control again in a number of these press briefings and as you know from the guidance put out by WHO for the different Phases, we have laid out the principles and the different disease control actions which can be considered by countries. And then these ought to be applied depending on the situation of the country and depending on the specific circumstances. So right now we are in a situation in which a number of different countries have instituted different kinds of disease control measures. One of the things that we are doing with these countries is contacting them to ask them about the actions being taken and also about the public health justification for those actions. This is under discussion with a number of different countries. I will not go into the specifics of the countries, and again as I have mentioned before, I do not want to talk about any actions taken by any one country.

In terms of the issue of community transmission, there has been a significant number of countries in Europe which have reported cases. The two countries again reporting the most cases have been the United Kingdom and Spain. We have been in very close contact with both of those countries over the past few days, including today, including last night, to make sure that we have a good sense of the situation there. Right now we do not believe that we are seeing community transmission in the same way that we are seeing community transmission in the United States or Mexico. In Spain, the cases are very closely related to travel. In the United Kingdom, there is infection going on in schools related to travel, but again when we talk about community transmission, what we are really looking for, is transmission not just in institutions but out in the broader community and we do not feel that we are seeing that right now. We will continue to work closely with the countries and any other countries reporting cases to make sure that we feel that we have a good handle on that situation.

**Emma Alberici, the Australian ABC:** Thank you for taking my question. I have two actually. First are you any closer to a conclusion on why some people have had such a severe reaction to this virus, particularly in Mexico, and others have contracted a very mild infection where the symptoms in some cases disappear with no treatment? And my second question is influenza does kill people around the world every year, what is it about this strain that is particularly troubling to you?

**Dr Fukuda:** These are very good questions. It is probably fair to say with almost any infectious disease that you see a spectrum of illness. And that is certainly true for influenza virus infections. That is even true for H5 infections, which we have been following for the past 4–5 years very closely. In that infection a large number of people have died from the infection. Nonetheless other people have had relatively mild infections. So with this new H1N1 virus again more people have had mild illness than severe illness. The reasons for that are not clear. I do not believe it really reflects differences in treatment, I do not think enough of these people have been treated with oseltamivir, for that to account for the differences that we are seeing. Most of the people did not receive treatment, some people did. But it is a basic question about any infectious disease. Why do some people do worse? And it is probably a combination of factors having to do with the individual, whether they are healthy, whether they have any underlying conditions, having to do with their immune system, having to do with conditions under which they get infected and so on. These are general reasons for why we see differences in outcomes, but we do not specifically know for this virus yet, and again this is something that investigators should be studying. This is something that is not going to be found out in weeks. This is really something that will take a great deal of study to get a handle on.

The second question is extremely important. Yes, it is true that seasonal influenza viruses kill people every year. Although there are not very precise estimates for the world, it has been estimated that up to about half a million people per year can die from seasonal influenza infections, and so for many of these people it is not a benign infection, so people have this image that seasonal influenza is mild. But the reality is, in fact, lots of people get hospitalized, lots of people die. With seasonal influenza we see that most the people who get really severely sick are either very young or old, or they are people who have different kinds of medical conditions, such as heart disease, lung disease and so on. Now the reason why we are paying so much attention to this virus though, is that the seasonal influenza viruses have been around and have been circulating for many years. And so we understand their behaviour and we know that most people have had previous infections and have some immunity to them; that is what makes them seasonal influenza viruses. But we also know that when a new influenza virus enters into the human population, and people do not have immunity to this virus, then the levels of serious illness and the levels of death can be higher than we see with regular seasonal influenza.

At the beginning of this kind of phenomenon where we are now, you can see that there is a great deal of attention being paid to monitoring the spread, there is a great deal of attention being paid to try to figure out what is the severity of this illness, and I hope you appreciate that we have been very careful to say that we expect the situation to evolve, and we are very careful to say that we do not quite know how it will evolve.

In the past when pandemics have occurred, and pandemics occur when you have a new influenza virus arrive, begin to spread around the world because it is being transmissible among people. We have seen pandemics cause relatively fewer death, and fewer serious illness, this was true in 1968. And we have also seen pandemics cause huge numbers of deaths. In 1918 the most conservative estimates of death, in that one year period, ranged from about 20 to 40 million people dying in one year from that infection. And we also know in that pandemic, it started out mild in the spring time and then over the course of several months became a severe illness.

We want everyone to understand that what we see now is important, but to remember that this is a virus, this is situation in which things that evolve, and which things can evolve quite differently and that is why quite much attention is being taken to pay attention to what is going on. This is why we are jumping so hard on it because if it stays mild and people stay healthy, then that is great, that is the best possible outcome. But if it does turn severe, then this is something that we have to know about it, it is something that we have to be prepared for, and it is something that we have to jump on.

**German Press Agency:** Yesterday you mentioned the increased amount of patients with diarrhoea symptoms and I was curious as to whether some of that has possibly to do with water and sanitation issues in Mexico and whether you are seeing that as well in the more developed countries that are also reporting these cases? And secondly given the improvement in today’s medicine is there really a chance of a repeat of 1918 or is that really not a possibility?

**Dr Fukuda:** Two good questions again. The reports of diarrhoea vary from country to country. Diarrhoea is being reported not just from Mexico, but for example, there are cases of this new infection associated with diarrhoea in the United States, for example. I think that what does vary though is that in some of the countries, the percentage of people developing diarrhoea is different. I think that this is still being sorted out. While some of the diarrhoea may be associated with other reasons, water, sanitation, I think that this does not really explain the phenomenon.

The second question was given that, our medical technology is just better than it was back in 1918, we have better antibiotics, we have better medical care than we have had, can we really expect to see at some point a repeat of that phenomenon? Hopefully not. But I think that one of the realities of these kinds of global health events, is that the current systems that we have can also be overwhelmed. When we went through the SARS epidemic a few years ago, in the places that were heavily affected we saw that the medical capacities could be overwhelmed easily. And when we see large numbers of people, being injured in other kinds of emergencies we can see the medical systems being overwhelmed also. So the technology is excellent, but that does not assure that the medical systems themselves can handle large numbers of people coming in outside of the usual range. So that is also one of the considerations that we have to work with.

**Times of India:** I wanted to ask you three questions. One is what does it say about the virus, if the average age of the infection is around 20s. And the second question is that today India was given a tip off by China that one of the passengers who came into India was in aircraft carrying an H1N1 infected person who was isolated in China. So how important is it that countries cooperate like this and give each other information? And the third question is how much do you think is this kind of infection a threat to people with HIV, because India has a huge burden of it.

**Dr Fukuda:** I think that right now as I started out the description about the clinical conference, we do not understand what is the reason for why we are tending to see younger people infected by this. There are a couple of different possibilities for this and I will just quickly go through them again. One of them is simply because we are early in the phenomenon and a lot of it is associated with travel, it is younger people who are travelling and that is why we are seeing it in younger people. A second possible reason is that in older people we are seeing some kind of protection. Perhaps because they have antibodies from earlier infections that are providing some kind of protection. Another possibility is that with influenza we often see it enter into younger age groups first and then later go into older people. We have not really seen that movement into older age groups yet. So these are all possibilities, I do not think that we have it sorted out right now, although it is relatively clear that we are seeing infections in younger people.

In terms of your second question, it is extremely important for information to be shared by countries. As you know, back in 2005, all Member States of WHO joined together to put into force the International Health Regulations, and one of the essential concepts of the International Health Regulations is that in order to deal with these public health emergencies of international concerns – of which a pandemic would fall into that category or other large infectious or non-infectious disease events – that you need cooperation among countries. One of the things which is essential for cooperation is that you have to make information available, you have to make it available to your neighbours and to other countries because everybody needs that information. That is the heart of the International Health Regulations. How do you deal with these large international events, how do you do it well, and one of the essential ingredients is that information sharing, making available what is known is critical. So this is again part of the reason why we push very hard on these global conference calls, this is one of the reasons why we are trying to get out information as quickly as we can, so people know. If people know they can deal with things better.

In terms of the third question of HIV, this is a very important question. The world is made up of a large number of groups of people who have different medical conditions. We talked about how chronic heart or lung conditions make people more vulnerable to influenza viruses in general. We know that people who have HIV infections can be susceptible to a number of other infections, and with influenza viruses, HIV infected populations are one of the groups of people who can be somewhat more heavily impacted than people who are healthy. So, another reason for us to monitor very carefully what is going, on as this infection spreads. We need to know are there different groups of people who are going to be disproportionately affected.

**Christine Chan, Hong Kong:** Could you please repeat once again. A formal reporter from India stated that there is a case of H1N1 isolated in China, case who is an Indian.

**Dr Fukuda:** This I cannot confirm. I do not know the most recent information on that. We can get back to you later on. I cannot confirm right now.

**Helen, AP:** You said older people might have antibodies from earlier infections. I was wondering if those people infected now by H1N1 virus, if they get immune and that means that in future outbreaks of this type of virus, they would be immune or they would be at greater risk of dying? And also we have not really seen any cases from the African continent. Does that mean that there are really no cases in Africa, or that there is no detection there? Last, could you comment on what US Health Secretary, Kathleen Sebelius said, that the virus appears not to be as strong as feared. Do you agree?

**Dr Fukuda:** For people who are being infected now and who recover from illness, it would be expected that they would be more protected than other uninfected people in the future, if they get exposed to the virus again. With influenza viruses, when you are infected, it provides some protection against future influenza viruses, similar to the one which infected you. But infection with influenza viruses does not give you protection for a long time. Generally, it will give you protection for a couple of years, and then the viruses themselves change enough so that it is kind of a new virus to your body so that you are susceptible again. The answer is that it would give you some relative protection.

In terms of Africa, yesterday when we were talking, we discussed how most of the infections right now are located in North America. There are infections that have gone to other countries in Europe, in Asia, and in South America, but by and large, most of the infections have still been in North America. When you look at the map you see that there are no large outbreaks reported in the southern hemisphere, but I think this is still very early in the spread of this virus. The southern hemisphere is entering into the winter months and this is one of the areas that we want to monitor most closely because it is quite possible that we will see activity there. At this time, Africa is not reporting any infections, but other countries in the southern hemisphere are not yet reporting any infections. So we will continue to monitor this.

About the strength of the virus, I think the fairest thing to say about the virus right now is that we are assessing it. Clearly many of the infections are mild for the individuals, but what we are really trying to get a handle on is that if large numbers of people get infected, what percentage of those people will develop serious illness or death. The reason why this is so important is that, with influenza viruses, if they spread around the world, you will see hundreds of millions of people get infected. You will see a very large number of people get infected, so if even relatively small percentages of people dying or developing serious respiratory disease, spread around the world can mean very large numbers around the world. For me, it is a little bit too early to make any pronouncements about what we are seeing. I want to stress that point that we need to monitor it.

**Jason Gale, Bloomberg:** Can you update us on the production of a seed vaccine? When will it be with vaccine makers and how easy is it to grow this particular strain in a laboratory?

**Dr Fukuda:** Since the very first appearance of this virus there have been some laboratories like the WHO Collaborating Centre in Atlanta – which is CDC – as well as some other laboratories that have been working on developing suitable viruses, candidate viruses to go into vaccines and there are a couple of different ways that this can be done. As soon as these viruses are ready, they will be gotten out to the vaccine manufacturers. So they can begin to see how well do these candidate viruses work with their production systems. I can't give you a precise date when that will happen, but that is being worked on very hard right now and I expect that, within weeks, these viruses will be out to manufacturers but I cannot give you precise estimates on that.

**Gabriella, Notimex, Mexican News Agency:** Are all the cases around the world imported from Mexico? Are you sure that not even one case is imported from the United States or Canada? Second question, are there any international regulations on how people held in quarantine should be treated. Seventy Mexicans were held in poor conditions in China: just your comments on that.

**Dr Fukuda:** I don't believe that all travel-related cases are related to travel just to Mexico. On today's conference call for example, I think we learned of one travel case being related to travel to the United States, but I think that again if people are moving around of course we will expect to see travel-related cases from different countries. This is something that can be expected to be seen.

In terms of your second question, there are two separate aspects to this. One of them is simply the issue of quarantine: when should one do it. I think this is something that is up to different countries, analysing their situation and in some instances, quarantine may be a reasonable control measure. Under any situation, however, and I will just speak very broadly here, under any situation, people who are in quarantine should be treated well. I don't think there is any question about this. Let's separate out the issue of quarantine whether it is a useful manoeuvre to do at that time from the treatment of people who are in quarantine. I think that here it is simply very clear that anyone who is going to be placed in quarantine, of course deserves to be treated well.

**Journalist:** You said that most of the cases are young people. Is it true about the death cases as well? And what do we know about the dead people, the symptoms and what were the worst symptoms of these people.

**Dr Fukuda:** Right now I don't have good information on the people who died specifically except to say that in general the investigators are reporting that similar to the other cases, many of the people who died tend to be younger people. But again, I can't give you the age range of the fatal cases or the specifics of that now. Hopefully in the future but I don't have that information now.

The people who have generally developed severe disease have had respiratory disease so these are people who are developing severe pneumonia, these are people who are requiring support on ventilators, their primary illness being respiratory.

**Stephanie Nebehay, Reuters:** Just going back to the issue of mass quarantines, I think in answer to the question you just gave you said that in some cases it might be a reasonable control measure. Can you maybe tell us a little more about how you would define that because it is happening in places besides China.

**Dr Fukuda:** Just to talk in general about quarantine, I will remind everybody what quarantine is. Quarantine is when you have people who are not sick, who are not showing symptoms and they go into an area that is quarantined off, so you minimize the contact between them and other people. The instances in which this kind of control measure is taken is, if you are very early in the spread of a disease, you may use quarantine to try to limit the spread of the disease. That is one reason why you may institute quarantine.

Another reason why you may institute it, is that if you know that people have been in close contact with somebody who is sick and you have a highly infectious disease, then it is a good way to identify those people who are at highest risk for getting infected, making sure you can identify them because you know that they are at higher risk for getting infected – making sure that they get treatment and those sorts of things. So there are different reasons when you can apply quarantine. It really depends on an assessment of what is going on and what you are trying to do at that time. So it is not a simple yes or no – you should do it, you shouldn't do it – you need to analyse the situation and then make your decisions about whether to apply quarantine.

**Time Magazine:** Just one or two clarifications. You said there were roughly 400 more cases now than there were yesterday. Are a lot of these new cases just a matter of a lab backlog going back in and confirming suspected cases, or is there still actually more active spread – are you seeing the reports of new cases slowing down in any way in Mexico or around the world.

**Dr Fukuda:** I think the increase in cases reflects both. We are seeing testing of specimens that were collected from previous infections and then the laboratory work is catching up to it, but we are also seeing new infections occurring. Both of these things are going on simultaneously. For the update figures for today, I couldn't break it down for you, I don't have it in detail, but we are definitely seeing both of those things go on at the same time.

**Journalist:** I want to ask about the vaccine production. In what condition will WHO recommend to switch the vaccine production from the seasonal one to the pandemic one? You are not recommending that at the moment and what is the reason for that, and can you tell me whether the pharmaceutical companies have enough capacity to produce both?

**Dr Fukuda:** There are two important issues about the production of a vaccine against this new virus. The first one is when do you begin production of this new vaccine, and the second part of the issue is when would you recommend stopping seasonal influenza vaccine. Right now we are in a period in which there is work going on to develop a new vaccine. That is going on. It started almost immediately and that will continue to push on. We are not at the point right now where we need to make the decision about whether to produce a new vaccine and whether to stop the seasonal vaccines. This is going to be done by consultation with a number of expert groups. There are some expert groups that advise WHO on immunization issues, vaccination issues, and in addition in this particular instance, getting the input of regulatory agencies, getting the input from a number of other experts and then getting the inputs from industry is all important to get a sense of what are the considerations in this situation, what types of vaccines might be produced and what are the triggers that should point to choosing one option or another, and then what are the implications of that because there are a number of different choices here that could be made. I can't give you a simple answer when will this be done – but this is the process through which it will be done.

In terms of capacity, there is much greater vaccine capacity than there was a few years ago, but there is not enough vaccine capacity to instantly make vaccine for the entire world's population for influenza. The capacity will also depend, in part, on what kind of vaccines are made so adjuvanted vaccines will stretch out the vaccine supply more than non-adjuvanted vaccines. Again there are different decisions about those sorts of things to be made. It is a complicated area, no simple yes or no answers here either.

# Transcript of virtual press conference with Gregory Hartl, WHO Spokesperson for Epidemic and Pandemic Diseases, and Dr Marie-Paule Kieny, Director of the Initiative for Vaccine Research, World Health Organization

## 6 May 2009

**Gregory Hartl:** Welcome to WHO's daily 17:00 o'clock press briefing. My name is Gregory Hartl, I am the Spokesperson for WHO and next to me is Dr Marie-Paule Kieny, the Director of the Initiative for Vaccine Research in WHO, who will be giving you a technical briefing on vaccine development. I would just quickly like to summarize the latest figures we have as of 16:00 Geneva time. We have cases confirmed in 23 countries that are officially reporting 1658 laboratory-confirmed cases of influenza A(H1N1) infection including 30 deaths. Mexico continues to have reported the largest number: 946 confirmed cases; increases have also occurred since last time we reported in: Canada, France, Guatemala, New Zealand, Spain, Sweden and United Kingdom. We can give you more exact figures afterwards if you wish, but now I will hand over to Dr Marie-Paule Kieny.

**Dr Marie-Paule Kieny:** Again, it's a pleasure to have the opportunity to brief you where the situation with the development of influenza A(H1N1) vaccine and also about the activities that WHO is conducting in this area. As per the figures we have provided last week, as you know we announced that the current capacity to make seasonal vaccine is around 900 million doses per year, and therefore, our conservative estimate is that this would translate between at least one to two billion doses of H1N1 pandemic vaccine, if it should be a pandemic.

For the time being, there seems to be confusion; we have maybe communicated two figures. Sometimes you can see us saying that it will take 4–6 months between identification of a virus and availability of first vaccine lot, sometimes we say 4–6 and sometimes 5–6. The reality is that 4 months would be for those manufacturers who can start immediately, who have been able to start immediate production, like the ones working with the wild type, who do not need to have a virus vaccine strain – which would have been made for this purpose – and who can start working as soon as they receive the wild type strain. For these vaccine manufacturers, it might be 4 months, for the others it likely to be more 5–6 months, and this is the vast majority of vaccine manufacturers.

About some discussion whether you would need one or two shots of vaccine to be protected against infection with H1N1, it is not know at all for the time being. Usually for seasonal vaccination, you are using only one administration of vaccine, although for small children, sometimes you use two doses. For H5N1 – avian influenza vaccine – it has been shown that you need two doses. For this new vaccine, nobody knows. It may be the case that the population has already some experience, some "priming" as we say, and has already encountered the H1N1 [unintelligible] – not the new one – but the human H1N1 seasonal strain, and because of that there is already some background level of immunity. If this is the case, it may be that one dose will be sufficient. But this still needs to be demonstrated, and it is only in clinical trials in humans with the first doses of vaccine available, that this will be completely clear.

Therefore, we will still need a few months to know whether we will need one or two doses. In terms of proceeding, as you know, the first step after isolation of the virus is to make what is called sometimes "seed strains" or "vaccine strains", "vaccine viruses". This is the starting biological material for the manufacturers. Efforts are still going on in the WHO Collaborating Centres, at the CDC and elsewhere, to generate these strains for the manufacturers and we still expect that these would be available to the manufacturers most likely during the second half of May. We will post on our web site, as soon as the date is for sure, as well as a list of laboratories from which these seed strains will be available and the date, and this as soon as possible.

We have communicated with all manufacturers already, and have assured them and taken all steps to ensure that these seed strains will be available to all of them who so request to the WHO Collaborating Centres.

While this is going on with the preparation for the manufacturing, what have we been doing in WHO? We have been discussing with the manufacturers – as a group – we have had a teleconference organised by one of the association of manufacturers, the IFPMA, where they have invited not only their members but also all the other manufacturers that are not part of the IFPMA but also making the influenza vaccines. This was held on Monday, and we have discussed all the issues that they wanted to know about: recommendations from WHO, seed strains, reagents… We have been informing all of them on the process and on the progress of the preparation.

We have been setting up an Advisory Committee that will provide policy recommendation to WHO on the use of this vaccine.

We are organizing, as I speak, a meeting that has been called by the Director-General in Geneva on 19 May with the heads of all the companies making influenza vaccines. The meeting will be convened by the Director-General and the UN Secretary General who want together talk to the manufacturers, and to discuss with them avenues to ensure more equitable access for developing countries of this vaccine when it will be available.

This will be a high level discussion with the manufacturers, appealing to corporate responsibility and to working together towards the increase of equitable access.

In the meantime, we have already started discussing with individual manufacturers about potential procurement by the UN agencies; for the UN, there are two agencies that actually buy vaccines for developing countries: one is UNICEF and the other one is in the Americas, the PAHO Revolving Fund. We are discussing with the manufacturers how and under which conditions they could allow the UN Procuring Agency, through WHO, to have vaccines as they come out of the production line. This is real time production for the benefit of developing countries.

I must say that the manufacturers that we have had discussions with, have been very forthcoming and we hope that we will be able in a few days – maximum weeks – to announce that some agreement has been signed.

The last area I would like to address before taking questions is whether WHO has already made recommendations, or will WHO make recommendations on switching from making seasonal vaccine to making the influenza A(H1N1) vaccine. What we have recommended for the time being, at present, is a technical recommendation to all manufacturers: to put everything in place to be able to start manufacturing vaccines.

We will have a quite large virtual meeting, with the first circle being the Advisory Committee itself, but then the second circle, being the manufacturers and the regulators to provide input to the discussion; and then we will have a third virtual meeting of this group on 14 May.

This group will be asked to provide advice to WHO on whether there is enough evidence to recommend, after the 14 May, that manufacturers should start to go large scale manufacturing influenza A(H1N1) vaccine. This is not a decision that the WHO Secretariat will need to take. We need to have advice of the best experts and to have a solid evidence to make this recommendation. We hope that this will be available for them – the evidence – to discuss and make a recommendation that will go to the Director-General, and based on this recommendation from the group, the Director-General may make a recommendation to the manufacturers to start full scale manufacturing. For the time being, we are watching the situation; this recommendation has not yet been made.

As to stop potentially seasonal vaccine production, again there is still evidence lacking to make such a big move into saying if we need or we don't need much less seasonal vaccine for the next epidemic season. We are currently collecting with the manufacturers all data and all evidence on availability of enough material to make seasonal vaccine now. Potentially a recommendation towards stopping production of seasonal vaccine may come in a few weeks, if it does. This is not a done deal; we separate recommendations on starting the initial steps: preparation, pilot lot, clinical trial. This recommendation is already out. The next recommendation might be, following advice from this group, whether to start a full scale production and a further recommendation might be again following review of other available evidence potentially to stop seasonal vaccine, but this is not out yet. With this, I will be very happy to respond to all the questions that I might be competent to address.

**Helen Branswell:** Two questions please, one is a clarification, Dr Kieny, I think in your opening remarks you said that there is capacity globally to make 900 million doses of seasonal vaccine. In your last press conference you said 700 million: I am wondering if you could clarify that. And the next question I would ask is about the discussions with the manufacturers to make available vaccines as it is coming off the production line, so immediately, for the developing countries, not forcing them to wait until later. In essence that would probably require vaccine manufacturers to vitiate or renege on contracts they have with countries such as Canada and others, for first round of pandemic vaccines in a pandemic. What are you going to say to them? They could be sued as a consequence of that.

**Dr Marie-Paule Kieny:** About the figures: as I am sure you realize it is very difficult to have a full knowledge of exactly how many because it depends what you take into consideration. So I had said 700 you are absolutely true, I have myself gone back to a study that was published by the consultant Oliver Wyman earlier this year in agreement with IFP manufacturers –WHO has collaborated with that also – and in the graph you can see that you are around 900 million. But between 700, 900, you know it depends what you count. In addition this is perpetually in evolution because plans are being built in a number of countries, they are being validated so there is an increase, a monthly increase if you wish, incremental increase of a capacity. So I had said 700 million that might have been the data by early 2009, it might now be 900 million.

In terms of real time access, yes, this is what we are trying to sort out with the manufacturers. We are well aware, and they are not hiding the fact that they have agreements with a number of governments to provide access to vaccine. Most of the time, the contract will say a number of doses per week or per month. We are discussing with the manufacturers where they are in terms of filling up their books. And to make sure that in what is still remaining as available, that we would have access not to vaccines in six months, but some vaccines will be accessible already in the early weeks, and months of the production. Of course the availability will be dependent on the manufacturers, dependent on the type of the agreement that they have with countries already, but we know and we have discussed with the manufacturers and most of them at least still have some window of opportunity in their orders. We want to make sure that we do not wait until this window has completely closed, and this is why we are taking a step now already before even having had a recommendation to go full scale to try to ensure access for developing countries.

**Eva Ussi, Grupo Radio Centro, Mexico:** I would like to ask you two questions if I may. Firstly, the influenza virus has already caused international hostilities particularly against Mexico, who have seen how Argentina, Cuba, Ecuador and China have cancelled flights to and from this country. China went even further and kept Mexican businessmen and Mexican tourists, around 70 people, secluded in a hotel. They were not infected, nevertheless they could only return to Mexico in a special flight. Mexicans feel hurt because they were laterally stigmatized for being Mexicans. This treatment was not given for the Unites States or Canada. This attitude actually contradicts the recommendations of the WHO, doesn't it? Second question: I would like to know how do you expect possibilities of a mutation; that the virus mutates in a new virus. In this case when the vaccine is available, will it still be effective?

**Dr Marie-Paule Kieny:** I will let Gregory Hartl respond the question about the IHR and the discrimination. I would not be sure to use the right words, so Gregory up to you and I will take the second question.

**Gregory Hartl:** We would just say that under the International Health Regulations, which is the legal framework under which the WHO and its Member States are responding to the crises, countries can take additional measures, other, than those recommended by WHO that they feel might be necessary to respond to a public health risk. However, countries adopting measures that are significantly different and/or interfere with international traffic must provide WHO the public health rational and relevant scientific information for those measures. We have begun the process of getting more information from a number of countries. WHO has not singled out any one country, but has requested information from a number of countries about the public health rational of their actions. This information will be circulated among IHR Member Countries who may, if they wish, consult with each other on those measures. We do remind you that the IHR does require that Member Countries treat travellers with respect for their human rights, dignity and fundamental freedoms. Nonetheless, screening of travellers, or other activities, as long as it meets these requirements can be considered as consistent and good public health practices, as required or recommended by WHO to prevent or mitigate a pandemic. The key is that they are carried out in line with or respect for human rights dignity, and fundamental freedoms.

**Dr Marie-Paule Kieny:** On mutation, of course as you know, influenza viruses mutate. So this is why we need to adapt the vaccines all the time. Before this press conference, I went back to the group responsible for the following up on virology with the WHO Collaborating Centres and it is still the case: the virus that is still circulating is similar with what was isolated first. For the time being we have no sign, that vaccine that would be developed using the strain first identified would not be effective. In terms of what will happen in the future is really difficult to predict. At one time it will drift, but it may drift next year, it may drift a lot, it may drift only a little. We do hope that the vaccine that will be made will still be effective as you know even against drifted viruses usually vaccines still have a reasonable effectiveness although it can vary, of course, if the virus is very much drifted. And we hope also that at least with the formulation of vaccine that has been developed using adjuvant, it seems that there is a better ability of these vaccines to induce protection against even drifted viruses. This is something that will be followed as the situation evolves. We are very early in the epidemic as you know, should there be a change in the recommendation of strain, we will of course announce it as soon as possible, but for the time being everything seems to indicate that the viruses that are being used right now to make seed strains are the right viruses.

**Deborah Berling, Global:** How many manufacturers have manifested interest in producing these vaccine. Are they mostly from Europe, the United States? Will most of these vaccines be patented? I have heard that there is another traditional way of producing the vaccines, a non patented way? Can you just develop a little bit more on that and how besides UN agencies, who is buying these vaccines, what are the other options for making this vaccine more available to the developing world.

**Dr Marie-Paule Kieny:** So how many manufactures? Well you have multinationals of course, you know we are always mentioning there are four very large multinationals who are making quite a lot of seasonal vaccines which is used in the world, but there are quite a number of other manufacturers. And we are discussing with all of them. For example in China there is a consortium of manufactures making influenza vaccines, four of them public manufacturers, there are also a couple of private manufactures, there are manufacturers in Hungary, in Serbia, and so we are discussing with all of them, because although they do not have the same individual capacity as a multinational, when you pull all these capacity together, you end up having quite a number of hundreds of millions of doses. We are working with them very much to see how we can help them also, help also the regulatory agencies in these countries to be able to license these vaccines on an emergency procedure. We are working with all of them, and we hope to be able to help them really contribute to the global amount of vaccines for availability to developing countries also.

Now in terms of intellectual property rights and on patents, the general technology to make influenza vaccine is very old. You know the technology you take an egg, you put a virus in, you let it grow, you harvest, you treat, you formulate… This is an old technology, there is no patent on the general way to make influenza vaccine. There are some subtleties, and interesting subtlety that is patented; so certain adjuvants are patented, certain others are not. Some adjuvants, even the well-considered adjuvants, oiling water adjuvant for some of those there are patents which are valid in the US for example, but this product would be free of rights everywhere else. So it is really a question of identifying where patent issues may pose a problem and where they will not. As I repeat, for the general technology, to make influenza vaccine this is patent-free.

About the seed strains or the vaccine viruses if you wish, as you know we discussed already: there are two ways of making the seed strains to make production of influenza vaccine using classical method. Either you do it using a technology called “reverse genetics” – this is patented by MedImmune – or you do it using reassortment**.** Reassortment is free of patent. For H5 it was not possible to make reassortment because the virus was an avian virus and was killing the egg. Now with this virus now, H1N1, which is not an avian virus, it is possible to make reassortment. Collaborating centres are making seed strains using reassortment and the manufacturers who do not have agreements with MedImmune will be able to use a seed strain that is free of patent rights.

In addition WHO has negotiated with owners of live-attenuated vaccine technology rights access to one of the two live-attenuated vaccine technology, which is available in the world, and we have sub-licenses ready for any manufacturer who is interested. We are currently discussing with a few manufacturers who are interested by this technology and we will be providing them full access to this technology as soon as possible for those who are interested. To sum up, there are patent issues for very specific applications or very specific areas of this manufacturing of influenza vaccine, and pandemic influenza vaccine production, but for the whole bulk, if you wish, of the aspects of production, this is completely free of IP rights.

**Kanako, Japanese newspaper:** Could you explain more about how the vaccine should be allocated to many countries once it is finally produced. And who pays? I am just wondering whether it is possible for rich mindful countries can buy lot of those, or not.

**Dr Marie-Paule Kieny:** You know, most vaccines are made by private companies. So a vaccine is like any other, in certain aspects, is like any other commodity that is produced by a manufacturer, a producer, and which is then marketed and sold to a private or a public customer. Now of course it is not completely like that because as we know there are a lot of issues about public health, about equitable access, and it cannot be considered simply as any other good. For the timing also, it is not known exactly which are the high priority target population in terms of age, in terms of specific health conditions, the people who should have access to the vaccine first. As I am sure you know that for, for example, for seasonal influenza vaccination, it is well-known, for example, that elderly people are one of the prime target for vaccination because for them the severity of the disease is the greatest. For this particular disease we do not know. Is it still the older people who will be most affected, is it the people with underlying health conditions, is it the very young, is it everybody? So first before really going on allocation and recommendation for priority use, we are still not there completely. Of course as soon as the data are available and coming up, in terms of the profile of the population which suffers more of a disease, there will be recommendation by WHO for priority use in certain population.

In terms of countries as I said, we are discussing with manufacturers, they are all aware of their cooperate responsibility, they want to help WHO as much as they can in view of the already existing contractual agreement to provide access to WHO to this vaccine and a further, after we have discussed and tried to secure as much as possible with the manufacturer, the other discussion will have to be placed at the political level between the WHO and governments, to see how this can be played out.

Who pays? Of course there is always a question of money and there is a transaction cost. For the time being the manufacturers that have discussed with us have always either been very open to donation, I can remind you that prior to the H1N1, WHO had had donation from two companies of 50 and 60 million doses of H5N1 vaccine. There are companies that are still considering very well donation to WHO for the benefit of developing countries, and also tier pricing. This is something that is really the norm, I would say, in the distribution of vaccine for poor countries, is that poor countries pay much less their doses of vaccine than the rich countries. Apart from that, who will pay? This again needs to be discussed, it could be donor countries, it could be charity, it could be development banks, and all will be put together to contribute to putting money forward. The first expense will be to buy potentially the vaccine for the ones who have not been donated, but the other one will be to help developing countries bear some of the costs that will be involved in the distribution of these vaccines.

**Julian Rush, Channel 4, UK:** Two things if I may. One is can you give me some indication of the capacity world wide to make vaccine, whether this means a decision to go for an H1N1 vaccine rather than seasonal vaccine, is it either/or, or whether there is the capacity to do both at the same time? And secondly, what criteria would you use, to make a decision to switch from seasonal flu vaccine to H1N1, given that it means loss of protection against seasonal flu, in order to be able to protect against H1N1 and the corresponding trade off that you have to make there?

**Dr Marie-Paule Kieny:** In terms of capacity, as we said, as long as we don't have a response to at least three variables. First is the yield: how well will this vaccine virus grow in eggs and how much of the active principle will be coming out; it is very difficult to say exactly what will be the capacity. For example, working with a first viral strain for H5 vaccines, which was a strain coming from Viet Nam, the manufacturer had really difficulties having high yield, and they could only have a third of what is the usual rate. With the Indonesian strain of H5, they could again obtain a yield as high as the one for seasonal influenza. This is virus dependent on a vaccine virus and this the first variable.

The second variable is: what formulation will work; will low dose work; would you need an adjuvant… According to all match of active principles you put in the vaccine dose, then also the capacity may be different.

And the third variable that I want to mention here that will impede on capacity is: how many doses would you need by person. Would you need one dose or two doses. If you need two doses of course you can only vaccinate half the number of people, but we hope that with this virus one dose will be sufficient. Before knowing that for sure, it is very difficult to say how many doses will be available. This is why we have said from the beginning that, being conservative, we think that there will be at least between 1 and 2 billion doses.

In terms of knowing if it possible to continue to make seasonal wild seed while already producing H1, it depends because you can't produce in the same manufacturing plant two influenza vaccines at the same time. This is why manufacturers for seasonal, for example, do the three strains one after the other. Some of the manufacturers have more than one production plant; so these manufacturers in theory could continue to make seasonal in one plant, and have one or more plants already doing the H1N1. It depends on the manufacturer.

In terms of a switch, I have seen somewhere in an interview somebody using me as the spokesperson and saying that "WHO was gambling on vaccine". I do not think we are gambling on vaccines. The decision on switch, as I said in my introduction, is not something that can be taken right now: there are a few factors that need to be taken into consideration in any signal that would say "stop seasonal". And among these factors would be a good knowledge of how much has already been produced. We hope to be able to have that by next week.

Also, about the severity of the disease – of this particular disease – as compared with seasonal vaccine, because you would want to have some seasonal vaccine of course in order to protect the high risk group. I remind you again that seasonal influenza is causing the death of between a quarter and half a million people a year. This is a serious disease, and we need to protect this vulnerable people against this disease. We would not want to have no seasonal influenza vaccine and we think we already have quite a lot of it produced.

These are some of the factors that will be taken into consideration by this policy advisory group when it will work towards making potentially a recommendation to the Director-General that at one point it might be the time to "switch", if you mean "switch" is "stop seasonal". But in the mean time, there may be recommendation coming much before that, could be next week, could be later also, it depends on the opinion of these experts and not on what I would think for example, or what the WHO Secretariat thinks, about starting large scale manufacturing.

**David Brown, Washington Post:** I have been unable to get from WHO or manufacturers an estimate of the number of doses of a pandemic vaccine that are already claimed under pre-production contracts. I would like to know: do you believe that right now the world deserves to know what fraction of a potential pandemic vaccine manufacturing production capacity is already spoken for and if you do believe that the world deserves to know, how much already has a claim on it, can you give us some estimate?

**Dr Marie-Paule Kieny:** Currently I do not know with any kind of precision. I hope that we will be able to know, as I said, by next week when we have all the data available from all the manufacturers. The reason why it is difficult to say is that it will depend on the manufacturer. Some manufacturer we know have orders already to coming not to what they can produce but they have orders which are already quite large for these vaccine doses. There are also manufacturers who either have such a large capacity that even with these orders they have a lot of capacity to offer, some others have no pre-purchased doses. It is really a mixed picture. Before jumping ahead and saying how many doses are being locked in contracts, we really need to have more data. There has been one manufacturer who has said publicly, in a teleconference with the other manufacturers, that their company had currently locked into contract enough vaccine to vaccinate a little bit over 200 million people, but this particular manufacturer has a much larger production capacity. Even though we may seem large, this manufacturer still has a lot to offer for other countries. It is not at all that we are hiding anything, I think that the reason why nobody is answering this question is that we don't know.

**John Zaracostas:** I was wondering and following up on my colleague's question, what assurances do you have on the production capacity, from the industry, the big companies, the independents and the government owned entities. We have not had that clarified by WHO for many months. Secondly, with reference to the antivirals: since they are proving effective, what about the production of antivirals? Do you have any information on that capacity? Or is it also an effective line of defence?

**Dr Marie-Paule Kieny:** About your second question: I have absolutely no idea. We have colleagues who are following this very closely, I am sure that if there is a press briefing on antivirals, they will be able to update you. I must admit my ignorance personally on what is the capacity for drugs.

How do we know (and I know that this is a question that you keep asking me) that actually what the manufacturers say is the true reality and if they do have this capacity?

First, what we now, is what they deliver on seasonal vaccine. And we know that they have produced for sure around 500 million doses of seasonal vaccine in 2009. So this we know for sure. What we know also is what they have been financed by some governments, including the US government to build its production plants on the US soil which comes over and above of what was existing a few years ago. We have not checked ourselves, but I would trust the US government to be able to check whether their investment in these manufacturing plants have been well invested and indeed whether these plants have been built. Although WHO has absolutely no capacity and no mandate to go and verify production plants ("show that you can make so many doses [unintelligible], if this is the case, or you can have so many eggs/week")… we really trust what the manufacturers tell us is the real truth. In addition, we know and they know that this is not the time to play games. They have always been very responsible and we do trust that what we say in terms of capacity represents indeed what is currently available.

**Vijay, The Economist:** Two clarifications, if you don't mind. First, you have mentioned the range of flu deaths per year at 250 to 500 000. We have heard Dr Fukuda earlier this week give the figure of only 500 000. I wonder if you could clarify what is the right number to use, if there is one, or there is uncertainty of how many flu deaths are per year. And the second question, the current manufacturing methods for flu vaccines typically use the egg-based approach, there are those who argue that cell-based approaches may provide a more rapid response. Is it possible that these are ready for prime time, or probably not in time to respond to the current crises.

**Dr Marie-Paule Kieny:** In terms of flu deaths, in purely epidemiological estimates of the number of any decease, you certainly know that there is a big uncertainty. The surveillance is not that precise, so therefore, you need to take a number of countries and then you do modelling, and then you extrapolate. Therefore, you cannot come with a point estimate and you can say, these many, even with a very high degree of precision, but actually there is always a range.

So why do I say 250 to 500 000, because this is the official numbers that we are using. We know that this is lightly to be underestimated. And why is that? This happens quite often and this is a topic of a lot of studies, especially in high-income countries, influenza is the major cause of deteriorating health in elderly people. You may have people who are quite old, ageing very well and who, because they have influenza one winter, suddenly deteriorate and after that, die of other causes. So how do you consider that? These are not influenza deaths but it is a cause of morbidity and further deaths. In addition, in many settings, flu is a syndrome that can be confused with other syndromes: it is a respiratory disease, when people die of pneumonia – is this an influenza pneumonia or is it strep pneumonia… it is difficult to know. So this is why it is thought currently by most experts that the number of flu deaths is currently underestimated. When we say between 250 to 500 000 – which is our current estimate – we can assume that actually the higher figure may be closer to the reality.

About cell culture, you are absolutely right. Most of the influenza vaccines available and used today are derived from embryonated eggs. There are few manufacturers that have development on cell cultures, very few of these vaccines are currently licensed. There are two or three manufacturers that do have licence product on cell cultures. These ones will be able to go immediately and make cell culture vaccines, but in terms of quantity of vaccines globally, this will represent only a small proportion of the amount of vaccines which will be available in the months to come.

**Andy Pollack, New York Times:** I have a couple of questions: First: you have mentioned that after meeting next week or soon as next week, there might be a decision on whether they go ahead with large scale manufacturing. I am interested in know what information will be come available between now and then that will lead to a decision NOT to go ahead with large scale manufacturing. The second question to follows-up with cell-based: there are various companies developing new kind of vaccine technology: DNA vaccines, sub-unit vaccines, viral particle vaccines, that they claim could allow for huge production in a relatively short period of time. These have not been approved for use yet. Would there be any circumstances where WHO would encourage or allow such production? Encourage individual country to take a gamble on some of these newer approaches?

**Dr Marie-Paule Kieny:** What might or might not come out of next week's meeting would be a recommendation that will be given to the Director-General and the Director-General will consider this and either issue or not. Usually she takes great consideration of advice and recommendations from this group. To recommend to manufacturers to produce large scale stocks of influenza A(H1N1) vaccine. The decision is not that of WHO as you know. The decision will be of the manufacturers to take. It is their prerogative to decide what they produce. So what information would be potentially available to say that is not yet the time? Well, **i**t is a question of saying how this infection evolves. There are new data, new evidence coming every day about the epidemiological pattern, about the likely percentage of population who might be affected or at least be infected, about the severity of the disease. All this information as it comes will be taken into consideration by the group as they make their recommendation.

Your last question is about new technologies and this for sure is a question that will come up more and more. What we would like to avoid is to say, does or would WHO recommend countries to take a gamble? Is really difficult to take a gamble to say, we don’t' know whether it will or not be safe, so let's gamble on safety. I don't think WHO nor any regulatory authority wants to gamble on this. You may remember that there were some difficulties in 1976 with the last scale mass vaccination campaign in the US against an outbreak of swine flu and nobody would like to repeat this experiment.

What about new technologies? They look very, very promising. There is no doubt that in the future (but when?) we will have other vaccine that will not be made in eggs, but we don't know how large the production will be in a small amount of time. The difficulty at this stage is that at the maximum these candidate vaccine have been tested in what is called Phase 1 clinical trials.

This Phase 1 clinical trial is a few doses in healthy adults usually. There is a big leap of faith to say that a few doses in individuals have been vaccinated and that you can take this very same product and inject it in millions of people. This is why for all novel vaccines, fantastic innovations, some of them are really great, but all these innovation need to be tested very thoroughly in clinical trials and the dossiers reviewed by National Regulatory Authorities before authorization to deploy them is given. This is why, to the best of our knowledge, none of these new vaccine is ready for large scale implementation at the present.

# Transcript of virtual press conference with
# Gregory Hartl, WHO Spokesperson for Epidemic and Pandemic Diseases,
# and Dr Keiji Fukuda, Assistant Director-General ad Interim
# for Health Security and Environment,
# World Health Organization

## 7 May 2009

**Gregory Hartl:** Welcome to the WHO's daily 17:00 o'clock press briefing here in Geneva, and I would like to handover to Dr Keiji Fukuda.

**Dr Fukuda:** Good afternoon everybody. Thank you for coming on a very beautiful day so I bet that you want to get outside as quickly as possible. As usual let me start out the press briefing with a quick update of where we are. As of 8:00 o'clock this morning Geneva time, we had 2099 laboratory-confirmed cases officially reported to WHO and these include 44 deaths – 44 people who died – 42 people in Mexico and 2 people in the United States. This represented an increase of about 441 people from the day before. That was the number that we had as of this morning. For all of you following the story you know that these numbers change frequently during the day so, understand that.

We remain at Phase 5. That has not changed and also the other important epidemiological feature is that we continue to see human-to-human transmission, community level transmission, primarily in North America. We are not seeing it yet anywhere else, so just to make it clear from the beginning.

There is one large question that I wanted to focus on today and again I am very happy to take any questions on this, because I think that it is an important issue to understand – to really understand. The question has come up to us a couple of times or a number of times: ”Why are we paying so much attention to this virus, especially when some of the reports coming out are saying that many of the cases are mild?” Again, I wanted to go into this question in a little bit of depth, so everybody here understands it.

I think that from the beginning of this whole situation a few weeks ago, we have said over and over, that the situation is evolving and we really don't understand how things are going to go in the future. That was true two weeks ago and you have seen over the last two weeks how it really was a time in which the virus was moving to a number of countries but became established in two countries, and it remains true right now. We still don't know how the future is going to evolve. But this is an important aspect because when we look at the world again, as we have gone over most of the activity is still concentrated in the northern hemisphere. So one of the questions about the future is "Will it go to the southern hemisphere and if it does, what will happen there?”. And then the second big question is "Will this virus change over time, or change over the next few months, over the next several months, perhaps a year, and become more dangerous or different than it is now?”. These are big unknowns that were there a couple of weeks ago, they are unknowns today.

But they are very important for WHO in terms of the global perspective of what is going on everywhere, not just in a single country, but everywhere.

If this situation continues to evolve, if the viruses do become established in multiple countries, outside of North America, if we do move into a pandemic, then our expectation is that we will see a large number of people infected worldwide. This is typically what happens in pandemic situations. If you look at past pandemics, it would be a reasonable estimate to say that perhaps a third of the world's population would get infected with this virus. You never know before hand, but this would be a reasonable kind of estimate. When you look at a third of the world's population – in recognizing that we are a globe of a little over six billion people – that is a lot of people to get infected. Even when, on an individual basis, illness for most people is relatively mild, if they are people who are dying, people who are getting pneumonia, and that is multiplied times that large percentage of people who get infected, then from the global perspective what we are concerned about is that they are still very large numbers of people who could develop pneumonia, require respirators, who could die. This is a kind of considerations that we have when we are paying attention to this big global phenomenon.

We have also discussed in the past, in a number of press conferences, when the southern hemisphere goes into winter time, this is traditionally the time when we see increased activity for influenza viruses, and so that is something which I think all of you appreciate. The second part of that though, is that when you look at the population in the southern hemisphere, it is a little bit different than the population of the northern hemisphere. We often have younger populations, we have younger populations in large developing countries, large developing regions and amongst those developing populations, we often have populations that are more vulnerable than other populations for a variety of reasons. This may be because of malnourishment, this may be because of war, this may be because of conditions like HIV infections, but there are a number of different reasons why some of these populations in developing countries can be more vulnerable. We have discussed in the past how – in the past – we have seen when seasonal influenza has hit some of these populations, what had been relatively mild for populations in the developed world, in fact was quite severe in its impact in the developing world.

These are very big concerns for us and we expect this kind of event to unfold over weeks and months. Pandemics do not occur in a couple of days. When we go back and we look at history – we are often looking at a one-year period – but really if you look over a two-year period that is really the period in which we see an increase in the number of illnesses and deaths during pandemic influenza.

In this current period, while we see activities go up in some areas, come down in some areas, we are watching to see whether there is a global spread of this, for us, for WHO, what we are mostly seeing, is that this is a time in which we can work with countries to be as prepared as possible. That is the bottom line. Our bottom line is that there are things that countries can do, that we can help them with, to get them prepared for this kind of potential increase in people getting sick. And this is why we are so serious about this event. That is what we want to prevent if something happens in the future and if it moves into the southern hemisphere, and there is more severe disease or the virus turns more virulent and we see increased disease in many places. So, come back to me with whatever questions you have if this is not clear. This is something that, I think it is very important to get right. It is not simply an issue of “Is it mild?”, “Is it severe?”, “If it is mild we should forget about it”. This is really something that it is important to convey to your readers.

Now the second issue I just wanted to touch upon before we go to questions, is eating pork. Again in earlier press conferences we have tried to make it very clear that we see this current situation as reflecting transmission of infections from person-to-person. Eating of pork does not cause risk to people for catching this infection. Eating pork is not a danger in terms of getting this infection. I just want to reemphasize that point again, because it has been very confusing over the past day or so. That was a pretty short update today, but let us go directly into questions.

**Martin, Science Magazine:** … happening in the southern hemisphere in the month ahead, especially in Africa where surveillance is presumably going to be very, very difficult and is poor. How will you know how many people become infected there?

**Dr Fukuda:** There are different surveillance capacities in the southern hemisphere. If we look at countries like New Zealand and Australia, the surveillance capacities are quite good. One of the things that WHO has been doing in working with its Member States, particularly because of the concerns about pandemic influenza over the past 4–5 years with H5, is to strengthen surveillance. In Africa we have been working very closely with our regional and country offices as well as the countries, to strengthen influenza surveillance there. In fact, there are now, I believe, eight laboratories in Africa that can detect these viruses. We have been working quite closely with our Member States there over the past few years to establish stronger network of laboratories and to increase that laboratories, and what we are hoping to do is to even move towards the building of Collaborating Centres in the future in Africa. There is a great deal of concerted efforts to strengthen surveillance there. In addition, there has been, I think a great deal of emphasis on improving diseases surveillance in Africa. So while, I think there is room for improvement, it is better than it was a while ago. In addition, one of the strong efforts that has been done with the collaborating centres in response to this infection is to get diagnostics test out to laboratories. I want to mention that over a 100 laboratories now have the capacity to diagnose this virus in laboratories around the world. These are some of the steps being taken for both the southern hemisphere as well as the northern hemisphere.

**Elia Nenguela, Associated Press:** You said there were more than 400 new cases reported since yesterday. I was wondering if these cases reflect a backlogue in lab testing or if it is really new cases? And secondly, if one third of the world population gets infected, in case of a pandemic, that would mean if this kind of influenza has the same mortality rate as a normal flu – which is 0.6 percent – that would mean that more than 12 million people could die. Do you agree with that estimate?

**Dr Fukuda:** No, I think the estimated deaths from seasonal influenza is lower than that, if you look at the data coming from places such as the United States, which has several decades of data on death estimates. But I think that the concept is right. If you take approximately two billion people – that would be the third of the six billion people – it just means that, if you have a virus that is capable of leading to serious illnesses, again you can have very large numbers of people getting sick and requiring hospitalization. I think the other thing to remember is that seasonal influenza itself is not a simple level of disease. Within regular influenza seasons we see very mild seasons, we see very severe seasons. The most severe seasons for seasonal influenza can be very similar in levels to pandemic influenza – to milder levels of pandemic influenza. There is a wide range of the impact of seasonal influenza that is important to understand in looking at this matter.

**Mr Bugaren, Reforma Newspaper, Mexico:** Two questions if I may. We are at the day 13 in this outbreak. Could you tell me your balance of the situation in Mexico, how are 13 days ago and which is the situation today. Do you think the international community should be grateful with Mexico for the drastic measures taken, knowing the impact in terms of economic and perception?

**Dr Fukuda:** Earlier on in this series of press conferences, I said that one of the things I didn't want to do is comment on a particular action being taken by any one country, or any countries as individual countries. But let me point out some of the things that the national authorities in all counties have to weigh when they are confronted with these situations. The kinds of measures that a country may take, such as the closure of schools, closure of meeting places and so on, is an attempt to reduce the number of people getting sick, reduce the spreading of infection in the local area. Often times the local authorities have to make those decisions before it is clear what the full effect of the disease on the population is. These are very difficult issues for national authorities to weigh. I think it is a little bit hard from the outside, simply to say: these are good or bad actions. They are very difficult actions having sat it on some of the kinds of discussions which countries have to take into consideration, because if on the other hand it turns out many people are very severely ill and they were not jumping on it early, they will also be criticized. I will just stop there and say that these are very difficult issues that the governments wrestle with and of course they try to make the best decisions that they can, given the information they have.

**Saki Ushi:** I have a question on who has a say on deciding whether this disease is being transmitted in community. Say for instance, Spain or the UK, will it be the country health authorities who would sort of decide that there is a community-level transmission, or will it be the WHO who would say "look guys it is at community level." And I am wondering, if would you care to comment on remarks by a top CDC official who said that "he would be very surprised if WHO didn't go into Phase 6."

**Dr Fukuda:** I can only comment on the official comment that is: am not quite sure if we know if we are going to Phase 6 or not, and when we would do so. It is really impossible for anybody to predict right now. But the question you asked is very interesting. It is clear, under the International Health Regulations, that the Director-General of WHO is responsible for calling for change in Phase. But the way that decision is made is to take in advice, and to build upon the scientific understanding. We are having these frequent conferences, science conferences, in part to get a sense of what do the scientists in the world think, how they are analysing, how they are interpreting the events. We go over the surveillance data ourselves. We talk with the people in the countries who are conducting the surveillance, asking them how they see things, what is their analysis. Because this is done in real time basically, it is an unfolding event, there are no easy numbers just to look at, there is nothing really to add up that is very precise. It requires getting information from a lot of different sources because that is the nature of unfolding events. There are no simple answers. If it was very clear, we would not have to make such kinds of contacts, but in fact we do make those contacts because we want to have a very robust feel for whether there is really transmission going on in countries and so we speak with as many scientists and investigators as possible. This kind of information comes into the decision making process. It is not just WHO sitting around saying: “Why don't we go up to Phase 5 or 6?”. It is just not calling up the country and saying: “Should we go from Phase 5 to 6?”. But it is really looking at all possible information that we can look at, and then using that assessment to decide – we now think that there is a solid basis – provide the advice to the Director-General so she understands what the assessment is, and then the Director-General can make the decision.

**Gopal Raj, the Hindi Newspaper, India:** You and others have explained how in 1918, the pandemic started mild and then became severe later on. Could you explain why that happened, was it because the virus mutated or were there some other reason?

**Dr Fukuda:** One of the absolute statement that you can make about influenza viruses is that they change. You know there are not so many absolute statement that you can make about these viruses, but one of them is that they change. They undergo mutations. Sometimes the genes inside of the viruses exchange with genes from other influenza viruses creating a new hybrid virus. This is just part and parcel of the natural biology of these viruses. A lot of times those changes do not make any real differences in terms of the properties of the virus. They do not make it more virulent, they do not make it more transmissible, they are just changes which are going on in the genes; but sometimes those kinds of changes make a large difference.

In 1918, based on the available historical information, it looks like the virus started spreading – certainly in the spring time if not before – but the effect of that spreading was relatively mild. There was not severe disease and then it became more noticeable during the summer with more deaths going on, but it was really in the fall time, when it exploded with large numbers of people getting sick and large numbers of people dying. Since then, there have been scientific studies looking at that virus trying to identify exactly why was that virus so virulent. I think that, the exact reason for why that virus was so virulent compared to other viruses is not so clear. It is clear that there are genetic differences, it is clear that there are things that you can see in the genome, which are a little bit different than other viruses. But to take another example, in the past few years we have been dealing with this H5N1 virus, again probably the most lethal of all influenza viruses, which has ever been seen. When you look at the genes, it is not exactly the same as the 1918 virus. So there are still things about what makes these viruses so lethal that we cannot really explain. We cannot tell you what combination of changes exactly, what combination of qualities within the virus makes one virus much more lethal than the other. But we just know that it happens. And so it is something that we have to watch out for.

**Jonathan Lynn, Reuters:** If the pandemic affects one third of the world's population, on the basis of what we know right now, what would be your projection for how many people would die as a result of that.

**Dr Fukuda:** I think again you cannot make those projections until you really see much more of what proportion of people get seriously sick, what proportion of people who are infected die. We said over and over again, we are in this period where the spread of the virus is evolving. Our understanding of what the clinical spectrum is, is evolving, more information is being collected. But I think it is very premature to make those kinds of projections.

**NHK:** Is there a possibility to shorten the time of the World Health Assembly of WHO?

**Dr Fukuda:** That is under consideration – sure, it is possible. I think that right now there are many people in many different countries involved in responding with this situation and so, if it becomes useful for making some of the meetings shorter then this is a practical consideration.

**Jamil Shade, Sao Paolo:** Two questions, please. Again on pork. Of course you were mentioning since yesterday, meaning the story that appeared with someone from WHO. Are you actually dis-authorizing what this person said, or can you clarify at least what he said about meat that is already contaminated? If you can clarify that to us. And secondly on terms of preparation, you said that this is the moment to prepare. Do you have any idea of how much it will cost, this preparation, either to your own budget – WHO budget – or to the UN budget, or to the Global Fund or UNITAID? Have you done any estimates so far of how much this preparation will cost?

**Dr Fukuda:** Let me take these two issues. No it is not disenfranchising what we said yesterday. I think it is really to clarify. The clarification is that we do not see that pork is a danger to people in terms of transmitting this infection. When pork is handled well, when it is cooked well, this is just not a threat to people for transmitting this infection. Yesterday and over the night some of the confusions have to do with that some of the points made by the speaker that were not so clearly understood, or were not so clearly picked-up. If you have meat that has gotten material on it, you know, that kind of situation, then of course you have to be careful. If you have animals that are dead and you do not know why they died, then of course you want to be careful with those kinds of animals, and not put them into the food chain. There are standard general ways to make sure that the food that you are preparing, that you are giving, is safe – regular standard procedures – and these are standards which should be adhered to. This is important. But I think this got confusing as to whether WHO was saying something different. But the bottom line that has been said in the past, that we really do not see eating pork as a danger – or process pork – it is a very clear message.

In terms of preparations, over the past 4–5 years with the pandemic preparations due to avian influenza, there have been significant numbers of dollars provided by the donor community. And again, in the order of a hundred, two hundred million dollars, I do not really know the precise estimates. It is really difficult to give you a single figure, that if this amount of money is made available, then the world is prepared because much of the preparations of the world really have to do with the training of people, making sure that people have the kinds of equipment, the kinds of information, the kinds of know-how that they need. Often times there is turnover in people who are working and so they go on to other positions, you have to continually retrain, there are things that have to be redone over and over again. You have to look at the plans that you made, make sure that they remain contemporary, that they are up to date. In a sense really being prepared for public health issues is a never ending job. Because the diseases change, the scope of the problem changes, the world changes and public health has to keep up with it. The bottom line message is that the kinds of dangers we face are changing in the modern world. Of course public health has to change to keep up with it. It is kind of a dog race.

**John Zaracostas:** I was wondering if you could elaborate a little bit on this 2 billion people that could be infected. We heard yesterday from your vaccine expert that 1–2 billion doses could be ready within a year. My question is, in the interim, since there will be a 4–6 month period before the vaccines are available, what capacity do you have of antivirals – the first line of defence. What is the capacity for antivirals that would be used in the first 4 or 5 months.

**Dr Fukuda:** Let me point out there  are really several lines of defence. In many ways, antivirals are an important one, but maybe not the most important one. To put this in perspective, when you are facing a new disease threat probably the single most important thing, more important than drugs or anything, is just information. If communities and families have information, if countries have information, that is the most powerful thing that you need in the beginning. Without that, you really are in the dark, you do not know what to do, you cannot understand what is going on. I think that you can see certainly in this response, the effort by a large number of organizations is to get out information as quickly as possible. This is probably to a greater extent than has happened in many outbreak situations in the past.

Then there are a number of other manoeuvres that can be instituted which do not require drugs, which do not require special technology. The whole idea of personal hygiene, being careful how you cough, washing your hands, that kind of etiquette, these are steps which can be taken by any country. Then there are manoeuvres such as isolation and quarantine that – we have talked about that – in certain situations can be very helpful. It depends on when you are using it, in one situation or another. And then you have other things such as antiviral drugs, hospitalizations and those kinds of defences that require materials. Here, in the past few years, the capacity to make antiviral drugs has increased a great deal. The manufacturers of these drugs has increased their capacity, and in addition there are generic drug manufacturers that also make these drugs. Again, I cannot go into absolute numbers, but to point out that these capacities have increased. But perhaps even more importantly than that there are a number of actions that countries and communities can take in terms of their handling of these kinds of disease threats.

**Dermot, Bloomberg:** Are there any indications or is there any anecdotal evidence that the virus is gaining a foothold in the community in either the UK or Spain?

**Dr Fukuda:** Based on the information that we have, and again we are in close contact with the countries, it is pretty much the status quo over the last few days. No strong evidence that the virus is establishing, has established the kind of community spread that we have seen in the United States and Mexico.

***One more point.***

**Dr Fukuda:** Everybody, one additional point that is important. I want you to not walk out of here saying that there is an estimate of 2 billion people to get infected over the next year or so. What I am pointing out is that in the past, when we have had pandemics, approximately about a third of people have gotten infected, but again in keeping with all things about the future, we live in a different world. It is the same, will it be greater, will it be smaller? We do not really know. This is a benchmark from the past, so please do not interpret this as a prediction for the future. Thank you.

# Transcript of virtual press conference with
# Gregory Hartl, WHO Spokesperson for Epidemic and Pandemic Diseases, and Dr Sylvie Briand, Project leader in the Global Influenza Programme, World Health Organization

## 8 May 2009

**Gregory Hartl:** Welcome to the WHO's daily press briefings, today Friday 8 May 17:00 o'clock Geneva. First, a couple of housekeeping matters if I may please, just to let you know that there will not be any virtual briefings on Saturday or Sunday, but we will be back on Monday, at 17:00 o’clock Geneva time, and to remind you that shortly after this briefing is over the audio file and a transcript of this briefing will be available on the WHO web site where of course you an find all the latest information about this A(H1N1) outbreak. I would like to hand over now to Dr Sylvie Briand, Project Leader in our Global Influenza Programme who will make an opening statement and then take questions from you.

**Dr Sylvie Briand:** Good afternoon and thank you very much for being here. I am currently working in the Global Influenza Programme, but since this crisis began, I am leading a group of experts and this group is called Science Knowledge Management and Standard. In fact this group comprises experts in various areas of influenza attention, including for example infection control, clinical management, occupational health, and environment and so on. I will talk today with you about some of the results of our work.

I would like to begin as usual by updating you with the latest figures that are available. As of today, 8 May 2009 at 2:00 pm we have had 25 countries reporting 2500 confirmed-laboratory cases of A(H1N1), which have resulted in 44 deaths. The news is that Brazil recently reported 4 cases. However, we see this increase in number of cases but we still remain in Phase 5, which means that we have no evidence of community transmission. We have new cases, most of them are imported cases from travellers, returning travellers or close contacts of these people. These figures are important of course, but the major figure of our work – I mean technical and scientific work – has been to try and understand better what is this new disease exactly? Because this is a new virus and of course we are still learning about this virus and how it behaves in human population.

Before having this crisis, WHO in the past years, worked very closely with Member States in the world to get them better prepared to face a pandemic. During this preparedness work we envisaged different scenarios, very worst case scenarios or slightly better scenarios, or more optimistic scenarios. Now that this new virus has emerged we need to look at the figures, look at the evidence, and try to see how we can now adapt these plans to face this new disease. This is why WHO is organizing conference calls with a number of scientists or people in the field to try and gather this detailed information on the disease. Yesterday, we had a conference call with clinicians in Mexico, because we are still trying to understand who are the high risk groups for this disease and it is important for us to get in touch with these people in the field who have seen the patients, who have treated the patients, and to get from their experience a new knowledge to be able to better address this problem in other countries.

Yesterday on a call with a clinician from the global network of clinicians that is usually working with WHO, together with the clinicians in Mexico, we reviewed one by one the severe cases that Mexico had in the recent weeks. This discussion was extremely interesting and important, because we were able to differentiate two types of people that are at risk for severe illness. One group was previously healthy young people, and they get sick and they experience a rapid deterioration of their health status and most of them have died from acute pneumonia. The second group were people with chronic underlying conditions such as diabetes, tuberculosis, cardiovascular diseases.These findings are really important because it enables us to better understand the course of the disease, and to also better understand what are the effects of the treatment. During this conversation also, it was very interesting to see that there was no major impact of bacterial pneumonia, but rather the Mexican had to see a viral pneumonia, which progressed into acute respiratory distress. So major cause of death was due to respiratory failure and major organ failure.

These findings are really interesting, because in previous pandemics we have seen two types of complications. One type of complications is a viral pneumonia, which is a disease due to the virus itself – severe disease due to this virus – and the other type of complications is a super infection with bacteria, so bacterial pneumonia. And as you understand these two different outcomes have an importance in public health, because then we know which kind of treatment should be applied to these different groups of people. From this, we understand that this disease is mild in the majority of cases, however, we will have some serious cases, mostly in people with underlying conditions, which is close to the pattern we see in seasonal influenza, but we can expect also some cases in people, previously healthy, who will suffer from this virus directly.

**Jonathan Lynn, Reuters:** Actually I have three questions. Firstly, can you please clarify what you said about the virtual press conferences over the weekend. Does that mean that there will be briefings in the media tent or no briefings at all. And then for Dr Briand, are you able to say anything about whether the World Health Assembly will be cut short to 5 days – as I believe is under discussion. Secondly we have heard discussions of revising again the pandemic alert scale used. Could you tell us anything about that?

**Gregory Hartl:** First of all, there are no briefings planned over the weekend. I say “planned” and obviously if something changes and we need to brief you, we will, but there are no briefings planned on Saturday or Sunday, no virtual press conference; the next one will on Monday at 5:00. Secondly, about the World Health Assembly, there have been discussions about shortening it, but no decision has yet been taken. Thirdly, yes we know of this interest or requests or discussions on revising the phases, but I think that it is not something that we are concentrating on at this moment.

**Richard Knox, National Public Radio:** With the cases that you have been examining with the clinicians in Mexico, can you say anything at all about the pathology of the cases which involved previously healthy young people. Have there been autopsies for instance, has anything began to be identified that might help to explain why, at least to these people, viral pneumonia resulted?

**Dr Sylvie Briand:** From the discussions we had with clinicians in Mexico, one important factor was that these people arrived very late to health care facilities, and therefore the treatment was applied probably very late in the course of the disease. This applies mainly to the first patients that they have seen, when this disease was not completely understood at the beginning.

**Frank Jordan, AP:** I would like to ask about the numbers that you keep publishing every day. Certainly, quite a few of these people will not have the disease any more, they will have recovered, so I am wondering at what stage are you going to stop publishing total case numbers and moving to current numbers or such alike. Secondly, we have heard a lot about discrimination against people from certain countries because there are outbreaks there. Will WHO be preparing any sort of report for Members at the World Health Assembly outlining what different countries have done, what the justifications are, and will you be making that report public?

**Dr Sylvie Briand:** In fact this epidemiological situation is evolving. We have in some countries ongoing community transmission, and it is becoming more and more difficult to track all the cases. For these countries, we will certainly move to a more monitoring mode, where the number of cases would be updated probably on a weekly basis, when we see that the trend is stabilizing. But for other countries that have been recently affected, I think it is still important to track each case and to try to contain as much as possible the transmission – if possible from the beginning – when there are only imported cases and contacts.

**Gregory Hartl:** In terms of your other question, according to the International Health Regulations (IHR) a country, if it wants to take health measures above and beyond what is recommended by WHO can do so, but it must justify those in public health terms. Often times, WHO will write to a country asking for justification for these measures. We have done that in quite a few instances already, I don't know exactly how many and we have received responses, and those responses are published on a web site for the national focal points for the IHR so that they are aware of what is going on. That is how the IHR work.

**Don McNeal, the New York Times:** Could you go into little more detail about the underlying diseases that might have been a problem, for example with asthma problem or any kind of underlying conditions?

**Dr Sylvie Briand:** When we say “underlying conditions” it means for us that these are the underlying conditions that are common for flu, even for seasonal flu. These people who have diabetes or cancer or immunosuppressive status, or could be also some respiratory chronic difficulties, all these are conditions that we see usually for normal seasonal flu, and these are the common high-risk groups let's say. This is why we are particularly interested to see if there are new high-risk groups that are emerging with this virus, so that we can better target our response – and treatment as well – especially if we have scarce resources, it is very important for us to be able to prioritize.

**Japan:** Could you elaborate a little bit about the “young healthy patients”, which used to come to the hospital too late. After people were hearing about what is happening, are there less people who came to the hospital too late? So are there only few people, young healthy adults, who became very seriously sick after several days, after hearing about this situation?

**Dr Sylvie Briand:** The reason why we mentioned this point is that because usually healthy adults, when they get flu – I mean seasonal flu – they usually have mild symptoms. It is very rare that young adults become severely sick with flu. This is a new feature with this virus. But the numbers are quite limited so far. In Mexico they are still reviewing the files and trying to assess the previous conditions of most of these young adults and for some of them, so far, there is no evidence that they had pre-existing conditions, but they are still investigating and trying to make sure that they have not missed any important conditions that were not reported in the medical file. This is why we are looking much more at these young adults, because when they start to develop severe pneumonia, it does not mean that they will necessarily die, something can be done, but the earlier, the better of course. And very simple therapy can help very much like oxygen, which is available nearly everywhere, can really save lives.

**Aline Gobet, CBC Canada:** I would like to know if you can provide us with numbers, the rate of death of normal flu, seasonal flu in the hemispheres. I would like to know first maybe worldwide, when it is severe or mild seasons for flu – normal flu – and is there a big difference between the south and the north hemispheres? Because if we look at the north hemisphere, there are a lot of very populated cold countries, but in the south hemisphere it is rather not very cold, even when they have their winter. So I was wondering if the question of temperature makes it less dangerous to have flu in the south hemisphere and if you could provide us with some numbers please?

**Dr Sylvie Briand:** In fact the numbers we have for seasonal flu vary depending on the years. Some years we have a very mild seasonal flu, and other years we have a more severe seasonal flu. Global figures are really difficult to get because each country is monitoring the flu season, and they provide their figures, but not necessarily on a regular basis. But to give you a kind of frame, in France for example, the number of deaths during seasonal flu varies from 5000–15 000 deaths, in the United States you can have 40 000 deaths depending on the years, so these are numbers, but highly variable. Regarding your question whether there are more deaths or severe cases in northern hemisphere than in southern hemisphere, this is a difficult question to answer. First of all, because of the variability between seasons, and secondly it depends also on the availability of data. Now, we know that we are looking much more into, for example tropical countries, where historically people thought that there was no flu because of the hot climate, but in fact recent studies show that there is flu in tropical countries. The difference is that they have probably – it's not as seasonal as in cold climate – but they have two or three peaks per year, and as limited data are available, this problem has not been completely measured and assessed yet. But there are more and more studies on this issue, and we can say that flu is really a global problem.

**John [Lawermann], Bloomberg**: We saw something from Mexico today are they saying that they had not the total measures that they did take: closing schools, shutting down restaurants. The number of hospitalizations would be close to 30 000….Would you comment on this in light of the US - I guess they are scaling back their estimation of the usefulness of closing schools.

**Dr Sylvie Briand:** Well, I think that this comes back to what I was saying at the beginning. The more we know about this disease, the more we will be able to have better control measures, targeted control measures and tailored control measures to the severity of the disease. When it started, I mean there were a lot of unknowns about this disease, about its severity and it was at the beginning a huge increase in the number of cases and severe cases in addition, so I think the measures that were taken were consistent with the information that was available at that time. As the disease spread, and we were able to detect more and more mild cases, then the picture changed. If the pictures changes then you have to adapt the measures and be consistent with the reality, not over react and just try to maintain the transmission as low as possible.

**Simeon Patterson, Tokyo Broadcasting System:** You eluded earlier to a debate, if we can call it that within the WHO, about whether to adjust the pandemic threat scale system itself, perhaps to take greater account of the severity of symptoms and so on. Where is that debate at the moment?

**Dr Sylvie Briand:** I do not think there is really a debate. The phases are the result of a consensus between WHO and its Member States. It is the result of a number of technical consultations where Member States were invited to discuss and to conclude that the phases that are currently in the *Pandemic Preparedness Guidelines* are probably the best way to approach this phenomenon. Then if you look at the *Guidelines* you will see also that WHO accepted to provide an assessment on the severity, in addition to these phases. The Phases are mainly based on the geographical spread of the disease and we will provide in addition to that an early assessment on the severity, which is what we are doing at the moment with the various scientific teleconferences we have been holding in the past few days to try and get more information on the disease and also to be able to have an assessment on the severity. But of course you have to understand that this assessment may vary according to the evolution of the disease and as we get more information on this disease as well.

**Rob Styne, the Washington Post:** Getting back to the cases that you reviewed with the Mexican doctors, I was wondering how many cases you reviewed and if you could break them down, what proportion of them were people who had underlying conditions, what proportion were otherwise healthy?

**Dr Sylvie Briand:** The discussion focused mainly on the severe cases who died, in order to understand first the progression of the disease, how fast severe cases die, and also to review the type of treatment these people have received and when they arrived at the care facilities. Of course, there are many more severe cases in Mexico and that means that we are still discussing with our Mexican colleagues to get a comprehensive review of the remaining cases but the first call focused on the ones that were the most severe.

**Sao Paulo, Brazil:** You said that you were the last few year in contact with countries to ensure that the level of readiness was high for a possible pandemic. I would like to ask what do you know about the level of readiness of Brazil and South America, and the weak points of their preparedness? The health minister of Brazil said that it is inevitable that there will be more cases in Brazil. I know that WHO said that it is too late to contain this virus and the thing to do now is to mitigate the effect. But I still wonder if it is not possible to contain in a country that has new cases and to avoid more cases?

**Dr Sylvie Briand:** About the level of preparedness of South America, I think that South America is like other countries in the world in the sense that since we have had the threat of H5N1 in avian influenza, the majority of countries in the world have embarked to intensive preparedness activities. Of course, you are never enough prepared but a lot of progress has been made in the recent years. South America has a good network of laboratories that are able to detect the disease and they have also in most of the countries a good seasonal influenza surveillance system. So the level of preparedness is quite good. Now the question about whether Brazil have more cases and can we contain it. I think what countries are trying at the moment is not completely to contain the disease, but at least to reduce the speed of spread. And this has major advantage because then you can control a little bit the increase in the number of cases and then be ready to provide more attention to the severe cases that may occur. The intention now is really to reduce the spread and make sure that you have enough time to better respond.

**Jerry [Riess], CBC TV Toronto:** I have three questions for Dr Briand. What obligation do local health authorities have to report cases especially those involving deaths? Is there a specific timeline that one would be expected to get that information to WHO and to the public domain? And do you feel that we are getting an accurate picture right now of the total deaths and cases around the world?

**Dr Sylvie Briand:** Within the International Health Regulations, countries are asked and requested to notify to WHO new cases of this disease in 24 hours. So far, countries have really contributed, reported fairly regularly the cases they have had. At the moment the picture we have, on the geographical basis reflects the reality. Sometimes, what is difficult is that you have always a timeline between the day of onset of the disease and the appearance of the first symptoms, and the day when you get the confirmation by the laboratory. So sometimes you can have some delay but in general the reporting system has been very effective and rapid.

**Shade, Brazil:** Perhaps if you could be more clear on the issue of the spread of the virus in the new countries such as Brazil. Are you saying that it is at the moment the best strategy for the country is to, let's say, reduce the rhythm of this spread and that containment is not a possibility at the moment. Can you be clear that this containment strategy is not feasible?

**Dr Sylvie Briand:** When initially we were talking about containment strategy, it was referring to the situation where you have the outbreak starting for example in a small village and then you contain the population of the village, give the population treatment and have this containment operation for enough days, let's say to have the transmission die by itself. But as you see now the situation is fairly different. These are travellers coming back with the virus and you can identify some of these travellers, but there is always a risk of some travellers that you missed and the surveillance system cannot track all the travellers and put them into isolation and track all the contacts. Of course this strategy is very effective to slow down and this is a situation we have seen in Europe because with intensive surveillance activities you can really contain this disease to the very few cases of imported cases, but the difficulty is to maintain this effort for a long period of time and also that you may miss some travellers that are in transit in other places and it is therefore quite difficult to make sure that you have identified all the subjects that could be infected with the virus.

**John Costas:** To come back to the evidence from the physicians who were working with the cases, if you could tell us a little bit the difference between the healthy patients that died and those with chronic illnesses. The doses of the interventions by the medical practitioners and also if some were put on respirators and still died; and if you have success stories of interventions where they have turned the corner to have a comparison.

**Dr Sylvie Briand:** Of course, I have discussed all these cases in fact. Some people were under mechanical ventilation, others not, some people had early treatment and others not and so on. That is why we reviewed all these cases to try to have a better picture of the different scenarios possible when somebody gets infected and has a severe pneumonia. What I think is important to understand is that people with underlying conditions are the usual people at risk for seasonal influenza. These are the people that are usually targeted for public health intervention during seasonal epidemics. The other group – young healthy adults – that have developed severe pneumonia may require more attention because these are somehow new high risk group, but fortunately among the severe patients Mexico had, these young healthy adults apparently were not the majority of the cases. But, giving you numbers is still very difficult because investigations are ongoing and especially on retrospective cases and we do not have at the moment all this information.

# Transcript of virtual press conference with
# Gregory Hartl, WHO Spokesperson for Epidemic and Pandemic Diseases,
# and Dr Keiji Fukuda, Assistant Director-General ad Interim
# for Health Security and Environment,
# World Health Organization

## 11 May 2009

**Gregory Hartl:** Welcome to the WHO's daily 17:00 o'clock press briefing here in Geneva, and I would like to handover to Dr Keiji Fukuda, who will give an update and take a few questions.

**Dr Fukuda:** As usual what I will do is give an update where we are in terms of the number, there are a couple of things that I want to go over, and then we throw it up with the questions. As of today, 08:00 am this morning Geneva time, the official number of laboratory-confirmed cases reported to WHO are 4694 cases from 30 countries, and this includes 53 deaths. We remain at Phase 5, as we have been for the past several days, and again community-level sustained human-to-human transmission has been documented in North America, Mexico and the United States most clearly, and we do not see clear evidence of sustained community-level transmission going on in other countries yet, although like you were very mindful of the many travel-related cases that have been reported from a large number of countries in almost all regions of the world now.

Now, there are two groups of questions that are coming up to WHO fairly often, and I think they reflect some ongoing uncertainty and questions about the Phases and about severity. What I wanted to do again was talk about both of those issues, and then we will throw it open to questions. In terms of the WHO Pandemic Alert Phases, as you know there are six of them, and these are Phases that WHO has worked with countries and scientists over the past two years really to improve. They have been around for a while based on the WHO Pandemic Preparedness Plans, going back to the late 1990s, but in an effort to update the guidance to Member States, what we did is to sit down with a very large number of scientists and public health people from around the world, and over the past one to two years, work on refining them, making them a little bit easier to understand and hopefully easier to apply.

Just to go back to the whole reason for why we have the Phases, why we have been working on pandemic preparedness, as you know one of the main dangers that we have been focused on through the past three, four or five years, has been H5N1 and avian influenza. This is really something that drove the pandemic preparedness process very hard, and that was one of the reasons why we have worked pretty hard to update guidance and clarify the Phases. And again, it is not just H5N1, but I think one of the lessons from SARS and the other global outbreaks that we have dealt with over the last number of years, is that the key to being better off is to be as prepared as possible. So this is really the whole drive behind this pandemic preparedness effort over the past number of years.

Right now as you know, we are at this so-called Phase 5, and in sort of dry terms, what this reflects is that we believe there is sustained community transmission, from person-to-person, occurring in two countries in one region, which is North America –which is one of the WHO Regions. We have not gone up to 6, and as we have gone on over and over again, I think with these press briefings, we have said, you know, we cannot predict the future, so it is possible that we will go up to Phase 6, we could go up there quickly, we could go up there after a long period of time, it is possible for us to go up, but it is also possible for the current situation to stabilize where it is now, and then it is possible that we will go back, down to Phase 4 in the future. So right now, all of these things are open.

If we do go up to Phase 6 – this question has come a couple of times – what does it mean? And I think here is where we begin to get into some of the confusion about does this mean that the pandemic or the spread of disease has become more severe? What it really indicates again, is that the spread of this virus has continued, has progressed and that it has become established in other parts of the world. That it has become established so that we are seeing community spread in another region. This is an important concept to get clear, it is an important point for everyone to understand: what going to Phase 6 would mean if we go there, is that the spread of the virus becomes established in another region outside of North America and is really going on at the community level.

Severity is a different characteristic, it is a different feature. When we talk about severity, there is a couple of different ways that it can be discussed and thought about, but I think this is a useful way to think about it: one of them of course is that there is disease severity, at the level of people. You know, regular, ordinary individuals, and the question for them is that: “If I get infected, will I develop mild illness, will I develop medium illness, or will I develop a severe illness?” So this is one aspect of severity: if a person gets infected, how many people are going to have mild illness, how many people are going to have severe illnesses. It is not really just a matter of how many people are dying, but it really is a matter of how many people develop different effects of illness, which can be considered severe. For example, it can be that people develop severe respiratory disease, severe complications and do not die. There are many ways that we look at clinical severity.

Now a different kind of severity, a different way to look at it is that we know that these outbreaks and these epidemics have an effect on countries. When they get affected, they can have their economies affected significantly, either through decreases in travel, decreases in trade, because people are concerned and they do not want to go out. There are a number of effects like that on countries, which again are a different kind of severity, but really have an impact.

When we take both of those things together, what is the disease impact on people, what is the impact on societies and countries, it is clear that the effect of pandemics can be different on different countries. If you come from a developed country, you may have one level of impact, if you come from a developing country, in which you have fewer resources, you can have a different kind of impact. In these different countries we have different groups of people, some of whom are more susceptible to disease, because they are vulnerable in a variety of ways, either because of things such as not having enough food, or perhaps having infections such as HIV be common in the population. There are a number of different reasons for why different populations can be more vulnerable than other populations. And it also has to do with the fact that some countries are able to respond to outbreaks and to epidemics better than other countries, because they have more resources, they have more things that they can put into place. We are really again aware that severity is not just a simple issue, it is not how many people are dying and that answers the question. It is really looking at all of these things and that is an important point to understand about what is severity.

In the past few weeks, we have been repeatedly asked: “Is this a mild event?” And I think that the response we have given back is that we are not sure right now. The situation is evolving, we see that infection has spread in some countries, particularly in the northern hemisphere, but we have not seen it spread to the southern hemisphere and if it goes there, we are not quite sure what the effects will be. We have said that we know that most people who get infected develop mild illness, but in fact some people develop serious illness, some of the people die. We know that among those people who develop serious illness and who die, we know that many of them are young and healthy adults, people who don't normally die from an influenza infection. This picture is changing, and so this is why we have stressed about the evolving nature of the situation, this is why we have really refrained from jumping to quickly to say: “this is mild”, “this is something”, because we know that we are seeing things change on an almost daily basis.

This brings up another question which has come: “Is the level of activity, is the response too strong?” Here again I want to point out a couple of things: we are just a few weeks into the overall response to the spread of this new infection. But when I went back and looked at one of the first communications put out by WHO, namely the first communication that went out on the web, we noted that there were 7 cases of this new infection that had been reported from the United States, and all of those were mild illnesses. The cases in Texas, and the cases in California. But we also noted that 18 cases had been reported from Mexico, and that in association with those 18 laboratory cases, that there were 854 pneumonia cases, which had been reported as part of that phenomenon, and out of that, there were 59 people who had died. This information was really quite worrisome to us at the time, and that coupled with the information that we are dealing with a new influenza virus and the knowledge about what has happened in the past, really put into motion a lot of activity by countries, by different institutions, including WHO.

Now that we are a few weeks into it, the picture is partly clearer. We have seen that in fact most people so far have developed a milder form of illness, but again we have noted that deaths are there and the numbers have increased somewhat. We have noted that we see the virus as being reported now from a number of countries not just in North America or Europe, but there are a number of countries in Asia which have reported cases, and we have seen some travel-related cases reported from the southern hemisphere. So you know there have been cases for example reported from places such as Brazil. This is unfolding, it is still going on, and we are still evaluating, we are evaluating the clinical features, we are evaluating the epidemiology, and the spread, and we will continue to evaluate what is the impact on both people and countries.

I think that this brings up the last point: much of what is going on now reflects the fact that so much planning and preparedness has gone on for the past few years. I think that it is still a confusing situation, we cannot come to you and say: “we understand everything which is going on”. But I do believe that if we had not had all of those preparations, if we had not worked so hard to get information out quickly, if countries had not been thinking about what to do in this kind of situation, in fact we would have had much more confusion and, in many ways, the severity would have been greater.

This is really an important point: it is often hard to see what it is that you have prevented by doing so much work, but it is exactly for this kind of situation. So if things turn out so that few people die, this would be the best of all possible outcomes. But in the meantime we will continue to work as hard as we can to make sure that countries are as prepared as possible. It is not just a state of whether you are prepared or not, it is something that you continuously have to work at, we will continue to work with countries on that, we will continue to monitor this, we will continue to provide as much information as possible, so that everyone has an assessment. I hope this addresses some of the recurrent questions that have come up to us about pandemic phases, about severity, and I hope it makes it a little bit clearer to understand why it is that events are preceding as they are, in terms of responding. Let me stop there and we will throw up into questions.

**Deborah Berlink, Global, Brazil:** President Lula said today that the flu has much less spread out than people thought it would be. Lula said also Brazil would continue to remain mobilized to combat the virus. But that brings two questions: first, do you [unintelligible] that the news about the risk of the spread of the disease and also about the risk about the severity of the disease has been exaggerated? Secondly, is there a risk that WHO has raised expectations so high that some countries might play the spread of the disease down?

**Dr Fukuda:** Certainly, in the southern hemisphere, it is fair to say that the spread of influenza right now is really very minimal. It is clearly at the beginning of the typical influenza season, so we have seen a few reports of seasonal influenza, and few reports of this new influenza A(H1N1) virus, so I think that is true. In terms of the severity in spread, I hope we have come across as trying to present a very balanced picture. One of the things that we have pointed out that the future is not possible to predict and there are many ways that event could turn out, and that knowing that there are many possibilities, things could stay relatively mild, things could become more severe, both of these are possible. Without that information, both people and countries cannot prepare as well as they can. It has been a useful information to get out there. We will continue to provide that information if it becomes clearer to us and we will certainly provide the clearest picture that we can.

**Frank Jordan, AP:** I have got two questions. First, leaving aside the Phase issue for a moment, have you got any reason to believe that the outbreaks that we are seeing in Europe at the moment are not going to develop in the same way as in Mexico and in the USA, where we have now very large number of cases? And second, the Director-General met today with the Heads of the World Trade Organization and World Intellectual Property Organization. A lot of people have been asking why there has been no push to produce a generic version of Tamiflu®. You know if this was discussed today and if not, why not? Why is there not a generic version of Tamiflu®?

**Dr Fukuda:** Right now we do not fully understand how the earliest events about how this disease appeared. Before the first cases were identified in California and in Mexico, it is not clear what was going on at that time. It is a little bit hard to know what will happen in Europe. But with Europe right now, we have a number of travel-associated cases where people have visited somewhere, came back and they have been directly infected; or people in contact with them have been infected. This is probably a little bit different on how it started in North America. However, having said that, what we can say about Europe is while in these other parts of the world such as Asia and South America, it is clear that people with infections are travelling to these different places and that it is quite possible for those infections to become established in those other areas. Whether it will develop exactly as it did in the United States, Canada, and in Mexico, is anybody's guess. I think the potential for it to become established either in Europe or in another places is there.

In terms of the second question about oseltamivir, which is one of the drugs available to treat influenza infections in general and this infection, in fact there are generic manufacturers of this drug. The manufacturer has worked with a number of other companies and so there are other manufacturers of this medication located in other countries. This was done, really because of the response to the H5N1 and the avian influenza situation and the push to have greater manufacture of this medication.

**Elizabeth Weise, USA Today:** I had this question on Phases: is there in epidemiology a gradation level for severity? And if so, would that be helpful in giving us a sense of where things stand if that exists?

**Dr Fukuda:** Severity is one of those terms and concepts that mean different things to different people. What is severe to politicians, is different then from what is severe to epidemiologists or what is severe to clinicians. The answer to that is that there is no simple clear epidemiological definition of severity. Here, in the way that we are talking about it, looking at it, is that our primary goal is to reduce the impact of disease on people and to reduce the adverse effects of that disease on people. The adverse effects are both directly the disease itself but also other aspects of it. For people, if it really makes functioning in their daily life and in their countries harder, that is also an important aspect to severity, but here one of the things that we are doing in terms of trying to get a sense of the severity between countries, is to focus more on the disease impact on people, because this is probably one of the things that is most easy to compare, from country to country. Different countries have different economic systems, different cultural systems, different populations, so it is a little bit hard to compare the social impact on different countries. But when people become infected, they may go to hospitals, may develop severe outcomes; this is a little bit easier to compare; so at least in terms of doing comparisons of severity between countries, one of the things we are focusing on first, is really the disease aspects.

**Mr Gold, German Press Agency:** There has been a bit of criticism regarding the public faith of how WHO has tried to explain the situation and reach out to people. I just want to understand if there is any plan to sort of change the alert system so that it reflects the actual degree of concern that should be as well as the geographical spread of it. Even though I understand that severity is something that is hard to pin down. Is there some way that there could be simultaneous explanations to people of both the level of concern as well as the pandemic thread?

**Dr Fukuda:** I think that certainly the level of concern of people in countries is an incredibly important aspect of any disease outbreak that you have to be aware of. You have to know what are people concerned about and what is really the level of anxiety. We definitely take those things into consideration when we are trying to give our advice, guidance on how to handle different aspects of the outbreak. But in the alert system too, we are also mindful for example, that hidden diseases can have a big impact on populations: even if there is not much attention about things, even if there is not much concern about them, there can be harm from disease. Here, we have things that we can measure. We can measure that the virus is moving from country to country, we can measure how many people are getting at least laboratory-confirmed illnesses, we can measure how many people are dying who have this disease. This is really an important part of trying to convey to countries: this is where we are. Which is what the pandemic Phases really tells you: this is where we are. And this is what some other things that you might do to be prepared. Again, we definitely will take and do take the level of concern into consideration, but at the same time, I think we have to also stick with having measurable ways to indicate where we are in terms of the spread of disease and to have measurable ways which everyone can understand in terms of what appropriate actions that should be taken given the state of the spread and the evolution of the epidemic. So we try to balance those two things, but we do want them to be very clear to people and how we are measuring them.

**Martin Benedict, AP TV:** Taking up on Frank's question about generic Tamiflu®: can you tell me whether the WHO is actively pushing for Tamiflu® to be made available generically to help poorer countries? Or are you happy for it to be regarded as a matter for market forces?

**Dr Fukuda:** There are a number of things which WHO is concerned about in terms of what countries should have access to. Antivirals are one of them, vaccines are another, information, guidance, clinical guidelines, and so on. There is a whole range of manoeuvres, materials, resources that countries should have access to. And antivirals are one of them. In terms of antivirals, there are a couple of different classes of them and oseltamivir belongs to one class, but there is another class of antivirals. In this particular instance, the current viruses are resistant to that other class of antivirals and so right now it does not make any sense to be talking about those antivirals to countries.

If they were sensitive to all of them, we would be talking about all of these different antivirals that could be used for this infection. Our primary interest is that, again, countries have access to the antivirals as much as possible: one of the interventions is to try to work with the private sector, generic makers as well as producers to increase a supply. One of them is to work with them to make sure that the access is possible and at as reasonable prices as possible. This is something that we work on with the manufacturing sector. It is not just to let the market take its course, but really we know there are things that can be helpful and how can we do it, or how can we make them more accessible.

**Helen Brownswell, Canadian press:** I wanted to get back to the issue of severity if I could. I understand the notion that this is not what the Phases are about. But I think it is very confusing to the public that we could be in this Phase with a disease that appears at the moment to be mild, and we could have been in this Phase with H5N1. It does not seem to people like there is an adequate reflection of the fact that a pandemic virus could produce a gamut of results in the population. Is there not some room for something like what the US has, this sort of hurricane scale, hurricane inspired scale in addition to having the pandemic stage? You also have at this time we see this as you know 1.2 or 2.3. Although we understand that this could change at some point. Is there any thought being given to that?

**Dr Fukuda:** First just let me talk a little bit about how severity does affect the way countries can make decisions in the choices they have, and then address the second part about how to capture that for countries.

Depending if one is at Phase 6, if the world is at Phase 6, or even if the world is at phase 5, countries have different choices to make about how they approach the control and different aspects of this infection. So for example if we were dealing right now with an H5N1 pandemic, if we were sitting here and saying we are at stage 5 or Phase 5 for H5N1, and the mortality was as high as if it was for the sporadic cases, which as you know has been very high, then I think that countries would be looking very hard at almost anything that could be done to stop the [unintelligible] infection and to keep the levels of infection down. I think that countries have been looking very hard at many community mitigation, so-called community mitigation manoeuvres, closing meetings, closing schools, those kind of actions and even though it would be very disruptive, it would be probably accepted by most countries if you were seeing large numbers of people die. On the other hand, if you are in a situation where you have a lot of infection, but in fact most cases remain mild and most people do not get sick enough to die, or end up in a hospital, then I think the range of choices changes. Then you really begin to balance what are the effects of disrupting society if I close schools, versus what is the effects of the infection on the population, and so on…. So this is how severity directly affects the thinking about decisions. WHO with the same group of people who were working on the Phases and working with us on developing the Pandemic Preparedness Plans have been working on the development of a way to grade severity. We have refrained from this point as the posting we are at a mild stage or whether it is medium or severe to that direction. But I think that we will be trying to provide this guidance as soon as we can. But again this has been part – an active part – of the pandemic preparedness thinking of the past few years in the planning by the same group of scientists and public health people we have been working with on other aspects.

**Gabriela, Notimex:** In relation with developing countries for example, the case of Costa Rica where there are 8 confirmed cases and 1 dead, could this reflect something about the severity of the disease in these countries or….?

**Dr Fukuda:** Gabriela, I think that right now with so few cases it is a little bit hard to tell. I think that, the number of cases in Costa Rica for example is still relatively small, and so whether that one death in that small number of cases means something unusual or it is just because some people will develop severe illness, no matter where they are, I think it is not clear to us right now. It's difficult to give you a clear answer on that right now.

**Richard Knox, NPR:** I wonder if you could give us some guidance on what you consider to be the threshold for sustained-communities spread. There are reports for instance in London of 5 cases at a school among the 39 confirmed in the UK, and probably elsewhere as well, and I think everybody right now is on the alert to – as you are – to see what may be happening, is either the same hazard or different from what we see in North America, so what is that threshold?

**Dr Fukuda:** Really, I think that the threshold for community spread is when you begin to see people who are getting infected who become cases, and it is just not clear where they are getting infected from. You know in the current situation where we have school outbreaks, we have a clear picture where people come in to the school with an infection, we know that students are having contact with other students for example, or siblings go home, and you can trace that kind of picture, and you can see how people are getting infected. But if you look at the community spread occurring in the United States right now this new A(H1N1) virus, in fact many of the cases cannot be traced anywhere. They are just getting infected out in the community somewhere and you do not know where that is happening. And that by and large is what we see with many respiratory diseases, when they are out in the communities. All of you have develop some kind of respiratory illness over your life, many times, and most of the times you have no idea where did you get sick, where did you get infected, was it at work, was it at school, was it while you were playing sports with somebody, it is not clear. When you are in that situation then you are really having a kind of spread of the infection go on in a community, whereas many times with influenza you may have a nursing home, you may have a school, you may have a building in which you have infection going on, but it does not spread out into the general community. So we are really looking for that evidence that has gone beyond the buildings and it is really out there in the community in a different way. So I hope that is clear.

**Jamil Shade, Sao Paolo:** Two questions, first also an attempt to solve a confusion: day by day we see let's say 1000 new cases being registered by your database, at least. How much of that can we say are new cases or are just lab confirmation of cases that sometimes are even solved already. Can you clarify that to us, perhaps a percentage, or at least an idea that both things are happening? Secondly, it is true that some politicians are trying to play down the disease at this moment. Is this a wise thing to do at this point?

**Dr Fukuda:** In terms of the new and old cases, it is clearly a mixture of both. I wish I could give you precise percentages of how many are old cases and how many are new, but in places where infection is established, again in places like such as in the United States, we know that there are new cases going on and we know that there is testing of older specimens – and this is also true in Mexico – but also in other parts of the world we know that these travel-related cases are people who are just recently identified. So we have both things going on right now.

In terms of whether to play down or not, I think that the most useful thing that can be said on this is to be aware that the situation can change and to be informed about that. And for countries to understand that the disease could stay mild, could go down, could go up, and also for both – us spokesmen, politicians speaking for the countries and people like me speaking for different organizations – just to keep reminding everybody that it could go up, it could go down, and that again in a situation where you are dealing with a new virus, a new infection, a new situation, it is important to remind people over and over again that we can't exactly predict where it's going to go.

**Mr Gonte, Times of India:** I have a few questions lined up. The first one is: you mentioned Europe and you said that it was mostly travel-associated cases. Indians love to travel to Europe at this time, so do you suggest that they put their plans to travel for a holiday on hold? If possible for some time or do you think it is safe to travel to Europe? This is the first question. The second one was: how many labs globally are equipped – diagnostically equipped to test cases – and is this a target that you have as to how many labs should, and are you equipping them to kind of test. And third and final question: do you think that the terminal scanners are good interventions in the airport or do you think manual checking is a better option?

**Dr Fukuda:** From fairly early on after we analysed this situation, we decided that WHO would not recommend travel restrictions and did not recommend closure of borders because we felt that the extent of infection had progressed enough by the time the event was identified that this would not slow down the spread of infection. So we do not recommend travel restrictions. In terms of the questions about laboratories, I cannot give you a precise figure, but I can say that over 100 laboratories in the world now have the capacity, the capability to test for this infection. I do not think it is possible for me to say how many laboratories should, I think as many laboratories as possible will be nice, but I can't give you a precise number there. In terms of airport measures, disease control actions by different countries reflect the decisions based on the considerations in that country. Over the past few weeks, I have not specifically said I think that countries should do this or that or have not commented on the disease control actions taken by countries, but I have pointed out that that there are a number of different actions that countries can take, and so leave it at that, but these are really country level choices.

**Question:** Have any national governments expressed opinions to the WHO about the desirability of staying at Phase 5 or desirability of going to Phase 6? And to what extent does WHO take on board those considerations? And secondly, you clarified very helpfully I thought, what it would mean to get community spread situations where you just do not know where people are picking up the disease? How many people would you require would that be 10, would that be 100 … mean just to get a ballpark figure. I have no idea whether it would be thousands or just a couple?

**Dr Fukuda:** Let me answer the first question: you know Member States have been in close contact with WHO and WHO has spoken with many governments, and there has been lots of exchange of questions back and forth. Certainly countries have expressed their opinions about whether, really more they have expressed a lot of questions about why are we at Phase 5, should be we at Phase 6, should we be at Phase 4. And I think that I would characterize it right now with that similar to the group of people in this room, everyone is really trying to get a sense of you know are we at the right place? And so I would characterize it that way.

In terms of the second question, in epidemiology, there are hardly ever exact numbers. I mean, you know what you are really looking for is something that is convincing, something that you cannot say: "maybe this is maybe just a quirk, this is maybe just a one off, this is maybe just a little bit of an oddity", you really want to have a fairly solid feeling that it is really in the community, because again, were are very mindful that going from Phase 5 to Phase 6 is a very important step, and it really would be interpreted that way. It is really looking for something that we feel it is solid. I cannot tell you whether that is 10 people or 100 people and so on.

**Question:** Last week-end there was a first confirmed case in Japan, and today the Chinese also announced their first confirmed case in mainland China. Both countries are very density populated areas, could you give me any comment on that? And do you think still the inspection at airports is still very effective, or government should focus – or not – on other measures?

**Dr Fukuda:** I think that both Japan and China are in the same situation as a number of countries, where travellers have returned and then they have been identified to have the new infection. Again I think that the main lessons for these countries – but really all countries – is that in this modern age travellers go to many different places and so infection can come in from many different places, and that the important thing to do right now in those countries as in other countries, is to keep on the watch for additional infections. It is one thing to have some travellers come in who are infected, but not have it spread, it is another situation to have it spreading in the communities as we are talking about. There are no specific unusual lessons for Japan or for China, it is the same lesson as it is for other countries that are in the same situation with their watching this and their monitoring, you know this is infection coming into our country.

And in terms of measures taken at airports, again this is a decision that different countries will make differently. It is very resource-intensive, it takes a lot of people, lots of staff to set up measures where you are looking at people who might have symptoms indicative infection, and then it is also true that you will have people coming in who may not have symptoms. It takes a lot of work and effort to set up good surveillance at airports, but again different countries would choose differently, and I think that is a reasonably approach.

# Transcript of virtual press conference with Gregory Hartl, WHO Spokesperson for Epidemic and Pandemic Diseases, and Dr Nikki Shindo, Medical officer in the Global Influenza Programme, World Health Organization

## 12 May 2009

**Gregory Hartl:** Welcome to our WHO's daily 17:00 o'clock press briefing here in Geneva. I will update your very briefly the figures that we had this morning already, but just to remind you that as of 06:00 o'clock GMT this morning 12 May, 30 countries have officially reported 5251 cases of A(H1N1) infection. The full figures can be found on the front page of the WHO web site. I would now like to handover to Dr Nikki Shindo, Medical officer in the Global Influenza Programme.

**Dr Nikki Shindo:** It is a pleasure to be here with you. I lead the clinical team of the WHO response to this new A(H1N1) outbreak. Since the start of this outbreak, we have been really closely looking into the clinical picture of this disease: symptoms and severity and factors for hospitalization and treatment. We have been working very closely with the US and Mexican health officials, and partners in the ground, as well as regional and country offices and clinicians. We have seen a spectrum of diseases from mild, typically what you call influenza-like illness, such as sore throat, fever, cough, running nose, joint pain, muscle pain, headache, malaise to a very severe form of this disease which is pneumonia, which sometimes require mechanical ventilation. The most important question from the beginning was: “Why only Mexico is having very severe cases?” The proportion of severe cases initially seemed to be very high in Mexico but not in the other countries. But as more information became available, the proportion of “mild” versus “severe” became very similar between these two countries – I am talking about the United States and Mexico.

In Mexico and the United States, there are mainly two groups that have been affected with severe illness. One group is the persons with underlying chronic medical conditions such as weak immune system, diabetes, cardiovascular disease, asthma. There have been reports of very severe illness and deaths in pregnant women. The second group is previously healthy, very fit young children and adults. The reason why these cases became very severe is yet unknown. We are trying to look into these factors, working closely with clinicians, especially from Mexico, to find the reason. We have been supporting WHO regional office in the Americas to develop clinical management guidance, and also guidance for the use of antivirals, to help the countries that are seeing an increasing number of the cases. Soon we will be publishing initial guidance for clinical management for this disease.

This guidance is to help doctors, nurses, and persons who will be caring for patients with this disease. We are highlighting the fact that most of the patients will not require hospitalization or antiviral therapy. We would also like to point out some very simple supportive therapy like antipyretics and hydration that are sufficient and also highlighting that aspirin should not be used because of the risk of Reye’s syndrome. The other important supportive therapy includes oxygen and antibiotics.

**Helen Brownswell, Canadian Press:** I was wondering, you just mentioned that the guidance is going to say that antivirals are not necessary. Are you getting a picture from the countries that have had cases, how often antivirals are being used now, and whether or not they are being perhaps overused given the severity of the disease or non-severity of the disease?

**Dr Nikki Shindo:** European countries that are mainly importing the cases have been using antivirals very aggressively. On the contrary, the countries like Mexico and the United States are trying to save the treatment for patients with underlying conditions and also the other groups at increased risk, such as pregnant women.

**Alan Milander, Excelsio Newspaper:** What I would like to ask is the following: there have been some studies published, for instance, today. They came to be text from the *Science Magazine* that says that there could be up to 23 000 people who are infected in Mexico and also yesterday, Dr Anne Schuchat from the CDC of the United States, said that the number of cases reported up to this point is just in the United States might be the tip of the iceberg, that is the way she said it. So do you believe that this trend also is correct for the rest of the world? I mean do you believe that there could be many more people infected and probably more people dead than had actually been confirmed up to this point?

**Dr Nikki Shindo:** From Mexico we heard that they prioritized, the health officials prioritized sample testing from very severe cases So for the milder cases, I am afraid, those samples have not been thoroughly tested because of the importance of the severe cases and trying to understand the spectrum of this virus in causing severe illness. Most of the samples that have been prioritized and have been tested are from very severe cases in Mexico.

**Jason Gale, Bloomberg:** You mention that Europe has been very aggressively using antivirals. Do you think, to some extent, it might be masking the severity of the illness in those cases?

**Dr Nikki Shindo:** It could. Because we don't have control study, we cannot really compare but we only see very small number of cases in Europe compared to the United States and Mexico. So we do not have a definite answer but it could be the reason why we are seeing less severe cases in the European countries.

**Laura McGuiness, Reuters:** I have two questions for you. First, I wonder if you could revisit the countries in Europe that have the largest pockets of infection so far – Spain and the UK – and tell us what you think in terms of the nature of the transmission there? And also, am interested in what your conclusions are about the mildness of the virus in most of the cases, given that many people will not require hospitalization or antivirals. What does that mean for the urgency of creating a vaccine for this strain?

**Dr Nikki Shindo:** We are only seeing the beginning of this outbreak. But perhaps soon it becomes more widely spread in covering or spreading to other regions. But so far, the data from the United States and Mexico suggest that about 10 percent, 9 to 10 percent of the positive cases, the confirmed cases require hospitalization. And the figures may evolve as more data become available, but at the snapshot we are seeing about 10 percent of hospitalization. This is clearly different from what we see from seasonal influenza. That is for sure. So that I think rightly urges the development and delivery of pandemic influenza vaccines because we are also facing the risk of having resistant viruses. Last year and previous seasons, we have seen widespread evidence of oseltamivir-resistant seasonal influenza. Given that we will have winter in southern American countries and also in the other parts of the southern hemisphere, there will be a risk of having viruses that will be highly resistant to antivirals.

**Martin Benedict, AP Television:** The media report that you all have seen this morning suggesting that out of every 1000 people who are confirmed with this disease, 14 of them will die. Can you tell us where that comes from and what is your view on that statistic?

**Dr Nikki Shindo:** The group that published this paper has been working very closely with WHO, and we have a group of modellers and statisticians working and looking at this issue, and of course the situation may change. But as I earlier expressed, this is based on snapshot statistics and based on the best available information at the moment. I think that it is the best we can reach and it gives us a good picture for planning.

**Deborah Berlink, Global:** I would like to know since you say that it could be that in Europe people are developing less severe illness because of antiviral treatment, what are you recommending? That people be treated immediately with antivirals?

**Dr Nikki Shindo:** It largely depends on the availability of antivirals and as a part of a pandemic preparedness plan, we urge countries to plan for prioritization and work on different scenarios, so that they can better plan for the later stage, when the virus comes back as the second or third [unintelligible], and plan accordingly. Not only antivirals but also other basic and simple medical supplies that can help people to feel better and recover quickly and also prevent severe disease, hospitalization, and consequently prevent death. It is not only antivirals but all the efforts combined and it totally depends on the availability of antivirals and on countries' pandemic preparedness plan.

**Lina Stalmack:** I have two questions. First I realize that in the US, infected patients are treated quite differently than in Europe or Asia. They are isolated and also people who had contact with them are closely watched and maybe the difference is that in the US there is much more infected people because the patients are not so isolated? And the second one is what do you think is the way of handling the disease, what is more appropriate?

**Dr Nikki Shindo:** Most of the Member States, more than hundred Member States, have developed their own National Pandemic Preparedness Plan and according to the Phase of the pandemic alert, the different actions will be turned on. For the level of isolation and public health measures, we have recommended different options and different actions, based on the severity and transmissibility of a pandemic influenza disease. So all the countries have been doing their own risk assessment and implementing the best they can do. Maybe in Asian countries, because of the experience with SARS and avian influenza H5N1 infection, they would like to stick to a higher level of security and preparedness and prevention with regards to this outbreak of A(H1N1). And the second question was the best way to deal with this disease? Yes, it totally depends on the local situation.

**Aline Gobelin, CBC, Canadian Broadcasting:** I have got two questions. First is there an obligation for all countries to report their cases? As the sickness is very mild, is it possible that some country, like Canada, could not report all the cases if it is just normal sickness. The other question is about the rate of mortality. I did not understand – the line was not very good – your answer very well when you were asked if it is true that for a 1000 people infected you could have a rate of 14% who would be severe cases and that seems enormous to me because it means 1.4% which is really a lot.

**Dr Nikki Shindo:** Yes, we are hearing from Canada that some of the patients did not even have fever: so there are mild cases and possibly asymptomatic cases. At this stage of the evolution of a pandemic, numbers themselves are not truly reflecting the true infection. The most important thing is whether the country has case or cases or whether the infection is seen at the community level. For example, the United States, they are not testing all the cases any more. They are prioritizing severe cases and also the samples from non-affected states. The cases count itself will not reflect the true distribution of the cases or infection anymore and yes, I think there are missed cases in the affected countries, such as in Canada, Mexico and the United States. There must be some cases that have not been captured as confirmed cases and we are already accepting the situation, and in some of the countries like United States it moved to the stage to monitor the spread of the disease and also focusing on testing the severe cases first to see whether the virus has mutated to cause more severe illness.

The second question, about case fatality rate, there are broad ranges of estimation at the moment because there are some assumptions and also it depends on the population that you choose. They are making estimates from specific population and close population that they can make estimates. But also we are hearing from Mexico from there early analyses and that number is slightly higher than when we heard it at the beginning, but it is changing. The situation is still evolving so as I told you this is based on the snapshot of the situation and this was the best estimate that we can give at the moment.

**Associated Press:** I would like to come back to what you said about antivirals being used more aggressively in Europe compared with the United States and Mexico. Don't you think that will contribute to the development of a resistant virus, if people are using antivirals so widely and would it not be appropriate for WHO then to urge European countries to use antivirals sparingly and just giving them to those that should be prioritized as you said – pregnant women or whoever.

**Dr Nikki Shindo:** We had a very interesting experience in the past two seasons with regards to the development of antiviral resistance in circulating seasonal influenza viruses. And the emergence of these antiviral-resistant viruses are not directly related to the usage of antivirals in the country. For example, in Japan, where per capita use of antivirals is the highest of the world, they had at the beginning a very low percentage of antiviral-resistant prevalence and on the contrary, so this phenomenon was first reported from where doctors do not normally prescribe antivirals to treat patients. So we did not see a clear relationship between the use of antivirals and the development and emergence of antiviral resistance. So the health officials are very aware of this event and sometimes treatment failure can give rise to antiviral resistance. We had this experience with H5N1 influenza: some patients from Viet Nam had developed antiviral-resistant viruses because of the sub-optimal treatment doses. So based on this information, at the beginning of emergence of such a new virus, public health officials may decide to use antivirals aggressively because that is what they have been preparing for and that is part of their Pandemic Preparedness Plan.

**France 5:** Last week Dr Fukuda said that one third of humanity could be affected by this virus. So if we take the example of France – who has around 60 million inhabitants – it would mean that 30% more or less of the French population could be infected, which could at least lead to 20 to 30 000 people who could die from this virus. Do you think it is a realistic scenario or do you think it is science-fiction?

**Dr Nikki Shindo:** The attack rate and the case fatality rate are completely different things. Sometimes, large numbers of population could be affected, but case-fatality rate could be low because the virus only cause mild illness, and it really is secondary depending on the health care system that you have. If you can get early attention from medical support and if you have underlying medical conditions, or you are pregnant, then you will get antiviral treatment because I know the French have one of the most high coverage by antivirals, not only oseltamivir but also zanamivir, which can be useful for pregnant women. That would greatly affect the case fatality rate.

**Donald McNeil, the New York Times:** Based on your observations of Mexico and the United States versus the European experience, are you recommending or not recommending aggressive early treatment with oseltamivir?

**Dr Nikki Shindo:** We do not really have a very strong position on the use of antivirals. It is part of the National Pandemic Preparedness Plan and, of course, we do not have any experience with treatment and clinical efficacy against this new virus. But the *in vitro* information with regards to the sensitivity of this virus against antiviral medicine suggests that this virus is resistant to what you call adamantanes (amantadine and rimantadine) but sensitive also to oseltamivir and zanamivir. Different countries have different strategies at different stages and also we would like to provide our risk assessment in order to help countries to better refine their strategy in the use of antivirals.

Part of this will be the guidance that we are soon publishing, and we will recommend to consider the use of antivirals for high-risk groups or the group of people at increased risk, depending on the availability. So still the countries have to make their prioritization: which population they want to save and we have very little data about the effectiveness of this track for the severe illness, which is late intervention. But because of the lack of immunity in a population, this virus can have prolonged replication in humans. There will be discussions on how to use it and how to make the best use of it. But we have very little information that is why we are requesting countries to provide us with their findings, their experiences with treating people. Mexico, Canada and the United States have started to treat some of the high-risk population with early treatment. We will perhaps get more confident, more information so that we can confident in early treatment or we can support late stage treatment. These are all questions that are thrown to the nationals and clinicians that are closely taking care of patients with this disease.

**Patterson, Tokyo Broadcasting System:** Just to draw two or few of these different themes together and appreciating that there is a lot that WHO does not know yet. It would sound like the recommendations would be either not to go for antivirals – except for high risk groups – or to follow the example of Japanese doctors, and I have lived in Japan, so I can vouch? them for doing this and that is to go very hard very early. Is that correct?

**Dr Nikki Shindo:** Yes, we just can give some very simple guidance. We know that early treatment is likely to work, but the only thing we know is from the experiences from treating seasonal influenza. Early treatment can reduce severity of the illness and duration of the illness. And also, from H5N1 disease – which is very, very severe – early treatment reduces mortality. These are the two things we know and I think that most of the clinicians would agree to follow these two concepts at the beginning. But more options we would like to know and we have little information about zanamivir. This information we would like to ask countries to support us to understand better about the efficacy and the use of antivirals.

**Gabriella, Notimex:** Could you elaborate on the risk of the mutation of the virus?

**Dr Nikki Shindo:** Virology is not really falling to my table, but so far because we have to worry about antiviral treatment, a clinical group is really focused on the particular virus genetics, which suggest the sensitivity and the resistance to antivirals. So far, as I earlier stated, these viruses – mainly the viruses collected from Mexico and the United States, and also from Canada – are resistant to adamantanes (one class of antivirals) and sensitive to oseltamivir and zanamivir. This is a very, very complicated issue when this epidemic moves to the southern hemisphere because in the Americas we have seen very, very high prevalence of antiviral resistance to seasonal influenza. And if it mixes, then it will give a hard time to clinicians to choose antivirals. So what we are going to try to do now, is to make a matrix with different influenza viruses and different antivirals, to create a quick-decision tool for clinicians and we also have to consider the circulation of influenza. We will work very closely together with our Global Influenza Surveillance Network in monitoring which seasonal influenza viruses are circulating in which area of the world, and what is our best recommendation for the use of antivirals.

I would like to highlight that at the moment we have not heard many cases with secondary bacterial pneumonia. So far, most of the severe pneumonia cases are likely to be caused by the primary viral pneumonia. But when we look back in the past pandemics, the major cause of respiratory complications was caused by secondary bacterial pneumonia, which we have not heard so far. Some very limited patients had developed a ventilator-associated pneumonia, which is a kind of nosocomial hospital-acquired infection, but these are very special cases. But as we hear of more cases we might see more bacterial infections, so we have to get ready for that, based on the past experience. Now, we are not recommending antimicrobial prophylaxis but if we are seeing or hearing more cases complicated by secondary bacterial infection, then we have to urge clinicians to look at the pathogens and use the appropriate antimicrobials, not only antivirals but also antimicrobials to treat these cases.

**NHK:** Could you elaborate again about how at this point WHO sees severity of patients. Can we say that WHO is changing its view about it?

**Dr Nikki Shindo:** I am in charge of clinical management. So I take very seriously each case and this is very, very unusual that we see very severe cases in previously healthy adults or young children. This is one thing we really have to worry about and also the pregnant women. If you count the cases, perhaps it is not as much as the number we hear from seasonal influenza because we estimate excess mortality including all secondary deaths and total deaths caused by seasonal influenza. It becomes very big numbers, but right now we are seeing almost direct deaths from this infection. This is totally out of the seasonal influenza season and it is already spring and getting closer to summer, but still the virus is spreading and causing very severe illness in previously healthy population. We are also hearing more hospitalized cases in the United States in immuno-compromised population and pregnant women. So we take this very seriously. We, the clinical team, take this very seriously. When you expand this to population then there is a different story but still we are seeing the beginning of this whole phenomenon and the important thing is that we have to monitor the situation.

# Transcript of virtual press conference with Gregory Hartl, WHO Spokesperson for Epidemic and Pandemic Diseases, and Dr Sylvie Briand, Project leader in the Global Influenza Programme, World Health Organization

## 13 May 2009

**Gregory Hartl:** Welcome to the WHO's daily briefing for today Friday 13 May 17:00 o'clock in Geneva. I would like to begin as usual by updating you with the latest figures that are available. As of 6:00 a.m. GMT this morning, 13 May 2009, we have had 33 countries officially reporting 5728 confirmed laboratory cases of influenza A(H1N1) infection. Those figures and more complete figures are on our web site. I would like to hand over now to Dr Sylvie Briand, Global Influenza Programme.

**Dr Sylvie Briand:** Before starting I would just like to clarify just two issues, because we have had a lot of questions on the resistance of this virus to antivirals I would like to clarify that this virus is sensitive to oseltamivir and zanamivir – the neuraminidase inhibitors. There must have been some confusion with the seasonal virus – the seasonal H1N1 – that has shown last year and the previous years some level of resistance to these antivirals, but it is not the case with this new A(H1N1) virus. This means also that WHO’s recommendations have not changed, and they are the same as before.

Today I want to talk a little bit about the severity of a pandemic and of the impact of a potential pandemic. As you know, WHO has increased the level of awareness from Phase 4 to Phase 5 recently and there are lots of questions whether this mean an increase in severity? In fact, I would like to clarify that the Phases that WHO has defined are mainly based on the transmission of this virus: is it a human-to-human transmission able to lead to community outbreaks? and what is the geographical spread of this virus?

But the severity itself is assessed by other means, with the gathering of more detailed data, because it is not as straightforward as it is for example for the geographical spread. And there are also lots of questions about: will WHO issue a kind of a severity index for the global spread? – I mean the global event. In fact this is an issue that has been discussed on many occasions in technical consultations before we issued the latest pandemic preparedness guidance, because it was really concerning. The assessment of severity is a key part of the information that will help national governments to plan for their response. Therefore, it is an issue that we have talked a lot about and we have also discussed whether it was feasible to have an index, at global level, as you have for example for hurricanes – where it goes on the [unintelligible] scale from one level to another.

In fact for influenza, this kind of index is not very helpful, especially at global level because severity will vary from place to place. What we have seen in previous pandemics, and even in the same country, is that you can have different levels of severity. And through out the pandemic itself, in previous pandemics, you have different waves and each wave can have its own level of severity. Therefore, to have one indicator to describe all this variety of situations was not very helpful.

What is important to understand is that severity is basically based on three components:

1) The first component is the virus itself: its virulence and its transmissibility. We already know some of the characteristics of this virus and of the disease it is provoking. We know now that most of the cases are mild and do not require treatment, however, we know also that there will be severe cases in people with underlying conditions, but also probably in young healthy adults. We know that this virus transmits easily and so, with this information, we can already have an idea of the severity of the disease itself.

But this is not the only component, what is very important to understand is that this virus and the disease it is leading to, will happen in a certain community, a certain population, so we need take into account the vulnerability of this population. What are the factors that enable us to characterize the vulnerability of a population? First, the pre-existing immunity because some of these viruses have been circulating before at a very low level, even if it is not the same virus, could be a virus that it is close to, and may have lead in some individuals to a certain level of immunity. This is an information we do not have at the moment because it is very difficult to assess the immunity of a population. But it may explain why the disease can be very severe in some populations and less severe in other population. So these are factors we will take into account.

2) The other factor – the vulnerability of a population – is also a pre-existing condition, underlying condition, meaning the proportion for example of people with chronic lung disease, proportion of people with chronic cardiovascular disease, diabetes, immuno-deficiency, etc. If the proportion of individuals with such conditions is high then we can expect a higher number of severe cases in this population as well.

3) The third factor that is really important also to understand the impact of a disease in a society, is what we call the capacity of the society to fight against this disease, or what we call also, the “resilience” of this community. The resilience is basically all the interventions that this community will put in place to reduce the transmission or to better treat the severe cases. At the end of the day, these interventions will have an impact on the number of deaths or the number of cases.

So you see, because severity is not one factor, only like the case fatality ratio for example, it is very hard to have an index, especially at global level. However, what we are trying at the moment is to gather as much information as possible on the virus, on the disease, and to provide this information to countries so that they can assess their own level of vulnerability and therefore put in place interventions that are needed to fight this disease. This is basically the work that we are doing at the moment.

**David Brown, the Washington Post:** I am wondering if one could generalize, as it is difficult to generalize, but it seems to me that the virus has a very high attack rate in young people and a larger than expected proportion of severe disease that requires hospitalization, which is very unusual for an influenza virus. Can you say that, is it possible to make this generalization?

**Dr Sylvie Briand:** In fact usually flu provokes a lot of mild diseases, especially in young people. Here, in this particular disease and with this virus, what we see in fact is that there are lots of cases in young people and we have seen, especially in Mexico for example, a number of severe cases in young adults. This is not typical of seasonal influenza. This is really a characteristic of this disease. Will this feature be found in other countries, this is something we cannot tell now, this is why we are cautious with our assessment of severity because we know that even if it is the same virus that is circulating in many countries at the moment, what we do not know yet is the vulnerability of each population, and so the disease can behave differently in different places in the world.

**Jason Gale, Bloomberg:** It sounds like the vaccine industry really had a question over the severity of the illness and that was something that they were trying to weigh up in order to determine whether they should switch to making a shot for H1N1 this new strain. And now it sound like there is sufficient evidence to show that this is actually more pathogenic than seasonal flu. Is that going to give them enough to sway them to producing a shot for this new virus when they have the seed vaccine available?

**Dr Sylvie Briand:** I think what has been said already is that the production of the new vaccine has started. We are not waiting to have more information. The seed viruses have been produced and we use this time to gather more information. Because, as I said, we have three factors about the impact: the virus, the vulnerability of the population and the interventions we can put in place to reduce the impact of a severe disease. All these factors will be taken into account in the decision. Not only the virus itself or the disease it produces but also looking at the population in which the vaccine will be distributed. We need to carefully target probably at-risk groups so that there is a best use of the vaccine and making sure that we are not exposing these people to maybe seasonal influenza as well. So we have to weight different factors and this is why the decision is not just a “yes” or “no”: it is more complicated than that.

**Jonathan Lynn, Reuters:** Could you tell us what it would take for the WHO now to reduce its pandemic alert Phase from 5 to 4?

**Dr Sylvie Briand:** Well, at the moment we have a number of countries reporting imported cases and also contact cases from these imported cases. So, we are still looking at the curve, how it increases, how it decreases and if it will lead to sustained-community transmission. If the thing goes down and we have then no more reported cases of imported cases, and if the epidemic goes down in countries that have currently a very high transmission level, then we will reconsider the situation. Basically, we are just looking at the figures and trying to see how things will evolve.

**NHK, Japan television:** Two questions. In your document of assessment of severity and you mention secondary attack rate. Could you explain a bit about this and the difference between the new virus and usual seasonal influenza. And secondly, yesterday Dr Shindo talked about 10% of hospitalization rate, how much is it higher than usual seasonal influenza?

**Dr Sylvie Briand**: Secondary attack rate is an indicator that we use to try to measure the transmission of the virus. From one person infected, how many persons will be affected from this person. So, we have a number of indicators to try to calculate how much this virus is transmissible and these indicators are really useful because it enables us to compare this virus with other seasonal viruses, and also this virus with other diseases that have epidemic potential. So we have some ranges and this enables us to understand more how it is transmissible.

The data we have at the moment on attack rates are clinical attack rates and we are only counting the cases that have clinical symptoms. More investigations are needed to really have an overview of how many people are really infected, because some of these people may not show symptoms and then are not counted. So we are still assessing these indicators of transmission of the virus. Regarding the hospitalization rate, this is an indicator for us to assess somehow the burden on the health care system. If we know the number of people showing symptoms and if 10% of these people are going to hospitals and are hospitalized, this is a good indication for countries that are not yet affected on how they can get prepared to attend such a number of patients. So, of course, it will vary from country to country because each country has its own health care system and the way they triage patients is different, but it gives you an idea – rough idea – of the burden that the health care system will have to bear in the coming days.

The point with seasonal influenza is more that we have different kind of patients, because seasonal influenza usually you have quite high hospitalization rates for elderly people and here I mean what we have seen at least in Mexico, is that young people can also be hospitalized and have severe forms of illness that require hospitalization. So this is the main difference.

**John Cohen, Science Magazine**: I understand that vaccine has some seed stocks to pile up and then full scale manufacturing. Is there a day, a week in time that WHO has set to make the decision whether to go to full scale manufacturing?

**Dr Sylvie Briand**: We are still having scientific discussions on how to assess the information that is available and so the date itself is not fixed.

**Marcel, Sao Paulo, Brazil:** I understand that it is difficult to assess the severity of this disease because it depends on the reaction of each population, but would you agree with some assessments made, including by US CDC, that the virus itself is less dangerous than was previously thought in the beginning?

**Dr Sylvie Briand**: There are in fact some characteristics of the virus, I mean they have identified some genes that are more virulent and can give more virulence to the virus itself. Especially people are often comparing this virus to the 1918 pandemic virus as a kind of standard for comparison. It seems in fact that this virus does not have this kind of characteristic. However, as I said before, this is not enough to say that it will be mild because first of all, apparently, it is quite a new virus so most of the population is completely naïve to this virus. The way a population will react to this new pathogen is something that can still be a quite severe reaction.

**Shade, Brazil:** My question is about the donation that Roche did yesterday to WHO of 5.6 million doses. We had no explanation of this donation, whether it was an agreement, if it was an agreement, what kind of an agreement was this, and does it entail any responsibility by WHO in this agreement?

**Dr Sylvie Briand:** I do not have the details of this specific agreement, but what was planned in fact is that we initially had a donation of antivirals but for adult doses, so what Roche has given recently is paediatric doses to have an increase on the reach of this donation, but I have no details on this particular agreement.

**Patterson, TBS:** You have mentioned different things that affect the vulnerability of certain countries and some of those things, such as pre-existing conditions or the interventions that a country will put in place, seem to me at least to be partly related to how wealthy that country is and what the health care system is like in those countries. Now given that Japan, for example – which is the country we represent – is a fairly wealthy country and has a reasonably good health care system, can we assume from that, that Japan is a less vulnerable country than say some of the others, say for example Mexico?

**Dr Sylvie Briand:** It is always very difficult to predict how this disease will behave in a particular country for the reason I mentioned before. What we want to highlight with this factor is that certainly some developing countries are more vulnerable in a sense that they have a high proportion of population that is malnourished and that are probably, is more, let us say, fragile for this particular disease. Part of this is the reason why we try to support even more these countries, to make sure that before this virus arrives they have put in place the necessary measures to, at least, mitigate its impact. But what is important to highlight as well is that some developing countries, especially for example in West Africa, have been used to cope with epidemics: meningitis epidemics, cholera epidemics, yellow fever epidemics and so on. So their health care system, even sometimes under-resourced ,is also quite prepared to handle crisis. So this is why we prefer to highlight the resilience of the country, the capacity of the country that is not mechanically related to their resources. They have also some capacities they can put into place and enable them to deal better with this threat.

**Nature Biotechnology**: I am just trying to understand the potential for vaccine makers in the medium term at least, to produce pandemic vaccines even presumably that they are already producing seasonal vaccines according to your biannual recommendations. And maybe you might explain that to me?

**Dr Sylvie Briand:** Part of the difficult decision is that we have two hemispheres that have flu at different times of the year. The seasonal vaccine is used one season by the southern hemisphere and then is used another season by the northern hemisphere. Usually the composition differs as well, so it is two production processes. We do not use necessarily the same vaccine in the north and in the south. This is well planned and it is in place, so manufacturers have these kind of production plans already ongoing. Adding the production of a new vaccine could be done separately or at the same time, and this is where the strategic decision is: we need to carefully assess the benefit of one vaccine for seasonal flu, the benefit of the vaccine for the new A(H1N1) virus, and balance the different benefits regarding the risks and the severity of each disease. This is why the decision is not on/off. It is really: let’s review the situation and let’s find the best way to minimize the number of deaths and protect better all populations in the south and in the north.

**Kyodo News, Japan:** I have two questions. The first one is about some guidance on severity: how long does it take if you could issue that guidance. Does it take some weeks or months to get it? Do you think you need to issue that kind of guidance before you change the alert level, next time? My second question is that today we had news raised by the Australian scientist that the new virus may be produced by human error. What is your comment on that news?

**Dr Sylvie Briand:** On the severity, rather than a guidance, we have already issued some considerations on the web site, and it is more a kind of concept paper outlining the key issues to consider. Then what we are doing is that we have a list of indicators that enable us to assess this disease and this virus, and they are the indicators that we are using when we discuss with countries and we try to gather detailed information. Basically we have this list of indicators and we use them to assess, first the disease itself, and help countries to assess their own vulnerability. Rather than a guidance, I would say, it is more a concept paper plus some operational tools to make the best use of the information we have and to better support countries in planning.

When we discussed the core guidance, the Pandemic Preparedness guidance, we said that the severity assessment would be part, of course, of the assessment and we want to put a lot of attention on that, but it was not linked with the Phases because of the reasons I have explained. It is difficult to have an uniform index at global level. We will continue to look at this severity assessment and to improve probably the details in which we can go about this disease and this virus, but in terms of linking necessarily Phases with severity, let's see if it is useful, but probably not so useful.

These are really two different concepts. The Phases were really to assess the geographical spread, and this spread can apply to any kind of pandemic, basically. It is a good indicator of the intensity of the transmission, but severity is something that may vary, that will vary, and so if we link it with the Phases, it will not enable us to make an adequate assessment over time. It will just fix the severity, which is not probably the best indicator for us to adapt our response and to tailor our public health intervention, according to this assessment.

**Gregory Hartl:** On the second question about this paper and the origins of the virus. This paper is, as we all know, publicly available and we have asked scientists in our Collaborating Centres and animal health specialists to look into this and see what evidence there is one way or the other, but it is way too soon to say anything on this claims, and in any case, WHO's main tasks at this point in the Phase of the A(H1N1) event are to assess the current risk, the spread of the current risk, the development of the current risk, and to help our Member States be prepared to respond. Those are what are the most important for us.

# Transcript of virtual press conference with Gregory Hartl, WHO Spokesperson for Epidemic and Pandemic Diseases, and Dr Keiji Fukuda, Assistant Director-General ad Interim for Health Security and Environment, World Health Organization

## 14 May 2009

**Gregory Hartl:** Welcome to the WHO's daily press briefing from today, Thursday 14 May 17:00 o'clock Geneva. Before I hand over to Dr Keiji Fukuda, I would like to do a couple of regular house keeping and one not so regular house keeping item, please. What is new is to let you know that today's virtual briefing will be the last virtual briefing for more or less a week. We will let you know when the next one is, but our Governing Body Meetings start tomorrow and consequently, we are suspending these virtual briefings for a period of time. However, we will be back, at the latest shortly after the World Health Assembly is over. With that, I would now like to hand over to Dr Keiji Fukuda, Assistant Director-General for Health Security and Environment.

**Dr Keiji Fukuda:** Welcome to the press briefing. As usual what I will do is give a quick overview of where we are in terms of the epidemiology, and then I will go into one or two issues, and then throw it open for any questions that anybody has. In terms of the numbers that we have received, the laboratory confirmed cases officially reported to WHO as of 8:30 this morning, we stand at 6497 laboratory confirmed cases. This is up from 769 more cases than yesterday, at about the same time, and this includes 65 people who have died from this infection and these cases have been reported from a total of 33 countries.

As it has been true from the beginning, the most cases have been reported from North America, with currently the United States reporting the most cases at 3552, Mexico reporting 2446 cases, and Canada reporting 389 cases. We continue to be at the pandemic alert Phase 5, we continue to be looking for evidence whether we have to move into Phase 6, but so far that has not occurred. In terms of the other countries – similar to the past few weeks – the other cases being seen in other regions and other countries are those cases associated with travel and then for people either being in contact with travellers, or perhaps household members, or outbreaks in places such as schools. So pretty much what we have been talking about for the last several days.

The issue I wanted to talk about in a little bit more in-depth today was something that we touched upon a few days ago and I just want to talk about it a little bit more today. One of the interesting things about this whole situation is that the amount of information available on what is unfolding is really probably unprecedented. There is more information available about the epidemiology, about the viruses, than has ever been true certainly for a global outbreak like this. As part of that push to get the information out, the gene sequencing information has been much more quickly available on these viruses than in any comparable event.

Over the weekend, WHO was contacted by a credible scientist, a credible virologist who indicated to WHO on Saturday that he thought, in his analyses of the gene sequences available, that potentially the viruses that were circulating were from a laboratory-derived virus. This was a hypothesis raised by the scientist and provided to WHO on Saturday, and this is not a scientist who is actually working with the influenza viruses. This is somebody who is able to go to the databases and take a look at the sequences available and, on his own analyses, come up with this hypothesis.

Because of the nature of the hypothesis and because of the credible nature of the scientist, we took this very seriously. Over the weekend, one of the first steps we did was to contact our Collaborating Centres. As you know we have WHO Influenza Collaborating Centres located in five cities. One of the first things that we did was to discuss the hypothesis and the evidence provided by the scientist, and ask them to take a look at that. However, because we are dealing with an influenza virus that is new, which origins are from swine, then what we did also on the next day was to contact FAO and OIE. FAO and OIE are sister organizations that have responsibility for the health of animals. They also maintain a large reference network of laboratories, and this goes under the name of AFLU. On the following Monday, what we did was then have a larger discussion with the larger group of virologists. These are animal influenza virologists plus human influenza virologists and there was a discussion. We asked them to look at the evidence and then to provide their opinion to us, was this a credible hypothesis or not.

This is a process that we have been going through over the last several days this week, and based on that evaluation by all of the laboratories, the conclusion is that this group of scientists feels that the hypothesis does not really stand up to scrutiny. In fact, the evidence suggests that this is a naturally-occurring virus and not a laboratory-derived virus. The paper that the first scientist brought up will be coming out. I think that the paper has not yet been posted and so we will have to see what the final form of the paper says and whether there is any additional information or so on.

The reason why I bring this up is because I think it is another example of what making information highly available allows to be done. This is a really interesting example where somebody, who is not directly involved with the investigations, is able to independently look at the information, making independent assessment, and then that same process which allowed this person to make the independent assessment, was then used to look at the hypothesis generated. In this instance, a scientist feels that there may be something unusual about the virus. We were then able to take other scientists with the same information, have it looked at, and looked at perhaps in more in-depth. And based on that process, the other group of scientists felt that the original hypothesis did not stand up to scrutiny.

This is really how the scientific process works and this is how the scientific process can work in the context of this kind of public health emergency. It is a really I think a nice example of what should be done. Other people looking at something, raising points, raising criticisms, and then the same process being used to address those directly. That was one of the more interesting uses of this kind of information in a real world example of what making information widely available can do. Hopefully, we will see this process applied over and over in additional investigations, in additional outbreaks as they come up.

The second point I wanted to address was in looking at some of the reports and in fielding some of the questions that we have had from media, I think there is a little bit of confusion about the antivirals. I just want to make two main points here:

1) WHO is not making any changes in its recommendations about antiviral use, and

2) there is confusion about whether we were seeing resistance in these new influenza A H1N1 viruses and we are not seeing any increased resistance.

Of course, we always remain concerned about the possibility of that. These viruses, like any other pathogens can develop that property, but we have not seen it and so it is something like many other aspects of this phenomenon that we will keep watching for. But we do not see it right now. With that I think brief coverage, let me just throw it open for questions.

**Alan Milander, Excelsior Newspaper:** It is probably an old question but still. You have said that there is still no evidence to say that the world is ready to go into a Phase 6. Yet there have been some reports, for instance from Brazil – and I know that Brazil is still in the same area, in the same region as Mexico and the United States – that there is transition from person to person. What exactly is the level of transmission that is needed, from person to person, in order to consider going to the next Phase?

**Dr Fukuda:** What we are looking for as information and as evidence to go from Phase 5 to Phase 6 is clear evidence that we are seeing what we consider to be sustained-community level, person-to-person transmission. So, for example, we know already that this virus can pass from person to person, that is very clear, but what we are looking for is evidence that in a country outside of North America, that in another region, the virus has established itself so that it is circulating in communities and infecting people, not just associated with travel, not just in one or two schools, something like that. The proof of the pudding, what we are looking for, is people who are getting infected who cannot be traced to anybody known to have an infection. Currently, many of the people who have not travelled we know have been in contact with the travellers returned. However, if we begin to see numbers of people who are getting infected, who have not had any contact with such persons, then this really becomes much stronger evidence that we are seeing community-to-community spread. Brazil is part of the Americas and we really are looking for this kind of pattern outside of the Americas, perhaps in Europe, perhaps in Asia, perhaps somewhere else in the Middle East or so, but outside of the Americas.

**Helen Branswell:** My question is one that probably you have been asked before, but I think it is one of those things that we need to revisit from time to time. The numbers continue to go up and yet we have not gone from 5 to 6. I am just wondering, out in the wider world, people are not as worried about this virus as they were a few weeks ago. I am wondering if you could tell me whether WHO is as worried, more worried, less worried than it was when we moved from 3 to 4 and 4 to 5.

**Dr Fukuda:** Certainly the global numbers have increased a lot. If you plot them up, you will see that it is almost a straight line with cases increasing, but the vast majority of those cases have been reported from the United States and Mexico, and these are areas in which we very clearly can see community spread. There is a wide geographical dispersion of these viruses in community activity, and the majority of the increase in numbers is still coming from those regions. In terms of the level of worry at WHO, I think that we are very similar to where we were at the beginning. At the beginning we made the point over and over again, we knew that it was a phenomenon that really required close monitoring, We know what passed pandemics have done, we know this is a new influenza virus, and we know that we are few weeks into this situation and we do not quite see what the future is going to bring. We do not know what the pattern of it will be if it continues to spread, we do not know what the pattern will be in the southern hemisphere, if it goes into Africa, and we do not know what changes will occur over time. Since we have seen changes occur over time in other pandemics and since we have seen the impact, or the severity of the impact, varying from population to population, since it is so early we know that these are potential changes that we have to monitor very carefully. Our message to everybody is, of course, do not over worry about these things, it is important to know it is serious to monitor and we are watching it very closely as are the other countries out there. It is something that requires following closely, on the other hand if we see changes in the severity, we will clearly let the world know about that. Whatever changes we see, we will pass that on. To characterize this, it is an event that is serious, that requires close monitoring, but most of the cases at this time continue to be mild cases, where people recover without needing hospitalization although there are some people that do get fatality and serious illnesses.

**Jason Gale:** Can you comment on the pattern of severe illness that we are seeing in otherwise healthy young adults and how that particular pattern places this event in a different context than seasonal flu for example?

**Dr Fukuda:** In the beginning a lot of people were characterizing what was going on as seasonal influenza, but in many ways I think that it is a little bit misleading. There are some features about this current phenomenon that are very different with what we see with seasonal influenza. For example, with seasonal influenza, all age groups get infected and in fact younger age groups get infected more often that other age groups. But the complications, the hospitalizations really occurred disproportionally among the elderly and among people who have chronic medical conditions. When you look at deaths for seasonal influenza, approximately 95% of deaths occur in people who are older, people 65 and above. You really see that all of the deaths – most of the deaths – are really concentrated in older people.

What we are seeing here with this new virus is that most of the people who have gotten infected so far are relatively young: they are younger than 60 years of age, the average or median age is somewhere in the 20s. When you look at the people who have died, these are younger people who are dying. Among those people who have died, part or mainly half of them are healthy people who have no predisposing conditions. It is highly unusual for young healthy people to die from influenza. This is a pattern that is different then from what we see with normal influenza. One of the patterns that has been noticed for other pandemics in the 20th century, there were three pandemics in the 20th century, is again that deaths occurred disproportionally more in younger people than they normally do. This appears to be perhaps one of the features of new influenza viruses has they emerge and they sweep around. The pattern of severity, who they affect is a little bit different from what we see with seasonal influenza. These are important differences and these are part of the reason why we take this so seriously. We do see significant and basic differences with how this virus is impacting people.

**Donald McNeil, the New York Times:** About the report that came in WHO on Saturday that turned out to be an error. How much damage do you feel that it did and given that this happens because gene sequences are posted publically where anybody, good scientists or bad scientists can read them. How do feel about posting sequences of the viruses publically? Do you think it is a good idea or do you think about going back to the old days and keep them privately. How do you feel about it?

**Dr Fukuda:** I think that, 10 years ago, we would not have been discussing because it would have been a very different situation. I think that when credible hypotheses are raised and they really raise important implications – a virus raised in a laboratory brings up several implications or possibilities – of course it causes our anxiety to go up very high, very fast. It is something that you have to think about and you have to think about: does this change what we are doing? Does this change how we would think about the overall situation? In that sense of course it causes a lot of anxiety and it leads to a lot of work that you maybe would not do if that was not there.

On the other hand we live in a time when there are many different hypotheses, many different rumours, many different accusations, many different theories which are posted on the Web which people bring up in any number of ways. In a sense I do not think this is damaging at all. I think what it shows is that if we have that information it brings up possibilities – and possibilities from very credible people – but it also points out that these possibilities can be addressed and they can be addressed in a really transparent manner.

Here I think is the key to the whole thing. We now live in an age in which it is really not possible to hide things. You know, things have to be looked at in an open way and it is all for the better, as far as we are concerned. It means that things come up that you have to address, maybe it means a little bit more work, but what it means is that you can also address it in a way which is pretty convincing to people. The scientist will publish his paper, it will be looked at by additional scientists – people will debate it and they will also be able to look at the evidence – but this is healthy, this is the way it should be done. This also allowed us to look at it in a very expedited way, go to people that we think are credible – very good scientists both in the animal health world and in the human health world – and address it directly on. This is much better than dealing with rumours in which the basis for the rumour is not clear and then dealing just with answers in which the basis of the answer is not so clear. I think this is the way we want to go.

**Frank Jordans, Associated Press:** On that point about the theory that was put out that you have now said it unlikely, are you excluding that possibility entirely or are you saying that on the available evidence, so far, it does not appear likely? The second question – follow up on one of my colleagues about whether we should be worried – since you are scaling back your media activity, that would give some people the impression that perhaps there are not going to be any major developments or at least you are not expecting many. Would people be right to feel a little bit calmer about the situation now than they were perhaps two weeks ago? Finally, just a quick word about the vaccines meeting today.

**Dr Fukuda:** I think that it is fair to say that in the world of science, nothing is ever totally excluded, nothing is ever ended. I think even gravity, thermodynamics, all these things are open for continual revisiting. So what is going to happen is that the paper will come out, there will be some continued debate. I think the real question is: “has it been addressed to a point where it has been sufficiently addressed” that we can feel fairly comfortable that we are not dealing with an unusual situation, and I think that is true. We feel very comfortable based on the analyses which have been done, based on the rigour in which it has been looked at, that we are not dealing with a laboratory-created virus. However, I do not expect that the debate itself will stop. I think that this will continue, but for the purposes of what we need to know in public health, and in terms of responding to this, the discussions and the examinations have been pretty rigorous, pretty good.

In terms of scaling back on media, it is not really “scaling back on media” so much, it is that we are heading into some large meetings. The Intergovernmental Meeting on Virus and Benefit sharing starts tomorrow and this basically involves all Member States, and then this goes on Friday and Saturday and then, beginning on Monday we go into the World Health Assembly. It is really a matter of, it is very hard to spread ourselves all over the place and so it is going to, I don't know, the media plan for large events – or additional large events.

In terms of the vaccine meeting, yes, one of the big issues about this overall situation is: “how do you approach the vaccine situation?” There are seasonal influenza vaccines that are made, there are H5N1 vaccines that have been under development, and then we have this new virus which is spreading around. The question is about, should there be a vaccine made to this new virus, what should you do with the seasonal vaccine viruses, a lot of questions like that, and if there are going to be changes made, then when should changes be made – now, in a few weeks, in a few months and so on. These are enormously complicated questions and they are not something that anyone can make in a single meeting or just sit around and decide.

The meeting today involved a large number of key players – actually when I came over here, I came directly from that meeting – involved a large number of key players both from industry as well as from the advisory groups to WHO, members of SAGE, members of one of the safety groups and so on. It is actually part of an ongoing discussion to look at what questions have to get addressed, how can you make those decisions, what evidence is there. There will be a series of meetings and this was one of those meetings to look at what kind of evidence is needed to make these kinds of decisions, to make these kinds of recommendations. There will be additional meetings that continue trying to get through all of these questions – so no big decisions, no pronouncements… - but part of this very complicated discussion.

**Agence France Press:** Just a follow up on the question on the vaccine meeting. Can you tell us when a decision might be made?

**Dr Fukuda:** There are really a series of steps and a series of decisions that have to be made. For example, the work on developing vaccines started almost from day 1. As we discussed as soon as a virus was identified, work began on turning the virus infecting people into a candidate viruses actively provided to a company, so they can test it out in their processes to see how well they might turn it into a vaccine. That started a few weeks ago and that work continues. Then there are some questions that then will come up which I do not think we have to address yet, because even if we address them, we cannot act upon them.

One of the questions is: “When and if should an A(H1N1) vaccine be made for this new virus?”. The reason why we cannot act upon it right now is that you have to have the viruses that can go into the vaccine before anyone can make the vaccine, and even once you give it to the company, they have to be tested and you cannot make the vaccine right away. That technical process itself will require several weeks before you could even start making a vaccine. That work continues and that is independent of any of these discussions.

Then the questions will come up: “Should we make the A(H1N1) vaccine, should we stop seasonal vaccine, should we be making both of them, what kind of combination might be reasonable?” Here, I think that as the A(H1N1) situation unfolds, we will get a better and better handle on what is the severity, what is the impact on people, and it will give us more information to make these difficult decisions. Because what is really going to be wrestled with is that seasonal influenza itself has a significant impact on people. This is not a benign infection, this is an infection that again is estimated to kill some hundreds of thousands of people each year round the world. There is a real trade-off if you just say we are going to stop making that vaccine. On the other hand, as we have discussed, this is a new virus that continues to spread around the world, may continue to evolve and so, if we also feel that this is becoming a really great, having a big health impact on people, you then have to weigh what are the relative benefits of making one vaccine or the other, or what are the relative benefits of making both vaccines. These are the kinds of questions that will be discussed as we go through these meetings and I think it is not possible to say that there will be a decision made by this date. It really is going through, I think, this painstaking and difficult process, but that is what is going on.

**Richard Knox, National Public Radio:** Could you outline the most important evidence that led to the consensus against the hypothesis of this might have been a lab-created virus? And, secondly, I want to be clear from what you said earlier, even if we do see sustained-community spread in South America in the coming weeks or months, WHO will not account that as a reason for escalating to Phase 6. Is that right?

**Dr Fukuda:** Let me address the second part first, then I will come back to your first question. The formal criteria from going from Phase 5 to Phase 6 – call for community-level sustained transmission in at least two different regions, in essence. South America will be part of the PAHO Region for the United States and it will all be part of one region. What we are looking for in order to meet the formal criteria is community-level transmission again in another region, outside of the Americas. Having said that, completely independent of the Phases, of course, if we are seeing a community-level transmission in Brazil or some part of Latin America, this would be an important evolutionary step in the whole thing, and we would be working very closely with the authorities there to try to address that situation. Two separate issues: one about the outbreak itself, and then one about the formality of the Phase change.

In terms of the evidence, some of the points brought up in the information conveyed to us by the scientist was that there appears to be an increase in lysine residues – it gets very technical – the lysine amino acids in the newer virus compared to some other swine viruses. Another point that was brought up is that on the phylogenetic tree, it looked like that this virus was out on a long branch, compared to some other swine viruses next to it. These are highly technical matters, but what is known about influenza viruses is that when you grow them in eggs – not have them reproduced in animals or in people – this can lead to an increase in lysine residues. But human influenza viruses, avian influenza viruses and swine influenza viruses are not the same. After discussion and looking at all the swine influenza viruses, it was concluded that the amount of lysine being seen was in fact very consistent with the natural increase in lysine being seen in swine influenza viruses. In fact, when the swine influenza viruses are put into eggs, you expect to see even more changes than we are seeing in these viruses.

Similarly, when it was looked at the long chain on the phylogenetic tree, it became clear that there are historical gaps in the information available on swine influenza viruses. But many swine influenza viruses are also associated with long branches on the phylogenetic tree, so there is nothing unusual there.

A third point that was brought up is that the potentially evolutionary rate of the genes in the new virus were progressing at a faster rate than other swine influenza viruses. But whenever you say that something is moving faster, it is in comparison to something. When it was looked at what it was actually being compared to, it was actually being compared to genes which in a fact were changing slower than what they normally do. So, again it exaggerated, it made it look that something was moving faster than looking at it in a broader way. It was very technical analyses like these, but looking at them one by one.

And then, in addition, when you look at the new swine influenza virus, what you see is that the genes – even though the grouping of the genes – is different than in other swine influenza viruses. The genes themselves have been seen in a number of other swine influenza viruses, so the genes themselves are not new. We already know from so much experience with influenza viruses that they often mix their genes and this is really felt to be consistent with a natural pattern of the swine influenza viruses. It was on a basis of a number of analyses like that.

**Mitamura, NHK:** Could you mention about the Intergovernmental Conference which will start from tomorrow? What kind of things would you like to talk with other representatives from the Governments?

**Dr Fukuda:** The Intergovernmental Meeting (IGM) tomorrow is one part of a series of meetings that has occurred for the last two years or so, in which all the Member States of

WHO in essence have been involved in a discussion about under what conditions should things such as novel influenza viruses – the kind we are talking about now or H5N1 – under what conditions should they be shared and in return, recognizing that there are a large number of countries, largely in developing countries, countries that have less access to resources, that are not often able to have access to many of the benefits that these viruses bring. Some of these benefits would be vaccines, antiviral drugs and so on… and so how can that be made more equitable.

It has been a very broad discussion about transparency, about equity – what is fair between countries – but also being mindful that when we deal with the viruses it is often in the context of a very real public health urgent situation. This is a good example of that, and that there are also very practical considerations which have to be taken into account. If you put all of those on the table, what is a good solution for balancing practicalities with these large needs for being more equitable, having more open access. This discussion tomorrow over the next days is a continuation of that discussion, in an attempt to get towards a larger framework in which all of this can be accommodated. In tomorrow's IGM we will bring this current experience into it, because this is not a theoretical experience, this is the real world unfolding. I hope that the countries would be mindful of this current experience we are going through, bring it into the discussions that they are having and, hopefully, will help them move towards whatever solution we will have from the discussion.

**Deutsche Presse, German News Agency:** OXFAM, the British-based charity, has released a statement today saying that the WHO should allow for waiving patents to drugs like Tamiflu® or others. I was just wondering if you might have any comment on this? They were saying that poor countries simply cannot afford to pay for the brand name drug and that the Indian company that has the right to produce its own version cannot sell it outside of India, so other poor countries cannot take advantage of that?

**Dr Fukuda:** First, WHO's position is that it would really like to have the antiviral drugs as well as the other essential materials like vaccines, to be as widely and broadly accessible as possible. This is part of the reason for the intergovernmental discussion that we are having. This is really the impetus behind many of the actions that we are taking. And this is really driving much our strategic approach for how we deal with this current situation. We are looking very much at the countries we think have the greatest vulnerabilities to this kind of situation, and how do we address that. That is really guiding much of our actions.

In terms of the antiviral drugs, about two years ago, several generic manufacturers were approached and asked about their interest in pre-qualification – meaning that being qualified by WHO to produce these drugs so that they could be made available cheaply. In addition, the current manufacturer of oseltamivir, Roche, approached a number of different companies and provided sub-licenses to those companies so that they could be producing them. However, over the past two years, in essence most of these companies or none of these companies were quite interested in producing the antiviral drugs. There was very little action, but recently again, because of the onset of this A(H1N1) and the spread of it, Cipla as mentioned in India, did begin the manufacturing process. It has been pre-qualified by WHO and so we hope to see the availability of the medications really increase as much as possible.

**Question:** I just wanted to make sure about the origin of the virus, now that you know that it does not come from a laboratory, is it most of the view of the scientists that it comes from a man in Mexico who was in contact with a swine and he got it from the animal itself?

**Dr Fukuda:** The virus itself originated from swine, and that is very clear when you analyse the genes and you see what kind of genes are inside this influenza virus. What is not clear is where did the actual virus originate from. I think that there is almost no evidence right now to be able to say where it originated from. Whether it originated in one country or in another country. Right now, this is probably an interesting question, not the most important question to address right now. I have no doubt that later on a number of scientists will look at it and try to figure out – is there way to figure out where it originated from? This will take looking at a number of viruses from the animal world and so on. But now it is fair to say we simply do not know where it originated from, geographically. Everything is speculation.

**Jamil Shade, São Paulo Brazil:** About the sharing of viruses and the discussion that will start tomorrow – actually the informal discussions started yesterday already –and it looks like that some countries are willing, or there is an agreement coming into place. The agreement supposedly would be that viruses and products that would be in the lab net, the "réseau" that WHO has, this will not be patented. But of course, the ones that are in the private sector would be still patented. Is this a good solution in your point of view or is there something still to come out of these negotiations?

**Dr Fukuda:** There are a number of informal meetings that are going on, so the formal meetings themselves will begin tomorrow, but certainly many informal meetings. To put this in perspective: this is very much a discussion among countries. This is not something that WHO will wade [unintelligible] into and say this is what we think you must do. This is really the countries talking about themselves or talking among themselves and saying: this is what we think is a reasonable solution. From WHO's perspective, there really is a balance of things that we hope are taken into account. One of them is simply that we have this urgent situation that has to be dealt with, and there are very practical issues that you can move quickly, that you can deal effectively with. The availability of the gene sequences which we started this discussion off, is a good example of what having information available rapidly means; surveillance depends on having warning as quickly as possible, so this is a critical aspect.

But I think it is also true that there are many countries which do not have access to things that are helpful to their populations, and all governments want to protect their populations. This is the balance to the discussion and that somewhere, the compromise between meeting both of those things, is really important, and it is important because if we get the right balance, it is an agreement which can be acted upon for a long time. If it is not a good agreement then, it is not something which stands the test of time. So the countries will talk it through and we will see where it goes, but I think these are the important aspects to balance.

# Transcript of virtual press conference with Gregory Hartl, WHO Spokesperson for Epidemic and Pandemic Diseases, and Dr Keiji Fukuda, Assistant Director-General ad Interim for Health Security and Environment, World Health Organization

## 22 May 2009

**M. Gregory Hartl:** Good afternoon, thank you for joining us here today, for this virtual press briefing, and also live here in Salle de Press III in the Palais des Nations in Geneva. We are doing it from here today because obviously we have been in the World Health Assembly here at the Palais this week, which is just finished, and at the end of this week Dr Keiji Fukuda is going to brief you on basically what has happened A(H1N1)-wise during the Assembly, more or less. Anyway, Dr Fukuda we will hand over to you in just a second to talk about A(H1N1). Thank you very much.

**Dr Keiji Fukuda:** Apologies, everybody for starting late. I have a little bit longer update than I normally give but we have not met for a week or so. What we have usually done in these updates on the H1N1 situation, is to go over where we are right now in terms of some of the numbers, I will give you a situation assessment and then go over a couple of issues which have come up over the past week, I think of interest to everybody and then we will just throw it open for questions as usual. As of this morning, we have 42 countries officially reporting these new H1N1 cases to WHO, and the number of officially laboratory-confirmed cases reported to WHO was 11 168 with 86 of those infected people dying.

We will continue to meet but one of the things I will point out is that as we go on into this situation, the numbers themselves will become a little bit more irrelevant. We now have countries that are moving away from counting cases individually because there are too many cases. So just to give you heads up, we will begin to de-emphasize the numbers because they will increasingly not reflect what is going on. In terms of some new information which has come out, there is a very nice article in the *WER*, the *Weekly Epidemiologic Record,* a WHO publication which summarizes the clinical information to date. This article provides an update on our understanding on the clinical symptoms and the clinical picture related to these new H1N1 cases.

The overall sense of the information is that it really supports much of the earlier impressions and ideas about this illness. Most of the cases that we are seeing continue to occur in younger people, i.e. people younger than 60 years of age. Most of the people who get infected by this virus develop a self-limited illness in which they do not need to go for hospitalization and they get better after some period of days. However, as we have noted from the very beginning, there continued to be a number of people who do develop serious illness. About half of these people - these are people who have to go to a hospital - but half of these people who are young and healthy with no underlying medical conditions and then, about half of these people are people who either have a condition like pregnancy or some other chronic conditions, which can be illnesses such as diabetes or lung disease or some form of immunodeficiency and so on. This is in-keeping with what we have seen earlier. Among the people who have developed mild illness, again a substantial number of people - about a third of them - developed diarrhoea which is a little bit different from what we see with seasonal influenza. In the people who are getting hospitalized we do not see this occurring as often. The report - I will not go into the details -- but it also contains much more detailed information about laboratory findings in those things, which will be helpful for doctors. I think that this information will be useful for clinicians around the world.

Now, if we take a look at where we are right now in terms of the overall global picture, I think there are a couple of things that are very clear. One of them is that the situation in the global picture still continues to evolve. I know that there is much speculation in the media for example, that maybe things are over or in some countries it looks like things are going down. But really, from a global perspective and from what we are seeing, this is probably fairly early in the spread of this infection. It is clear that the global picture continues to evolve and we expect that, over the next several months, we will continue to see spread of this virus and an evolving picture of the epidemiology.

I think it is fair to say at this point that there appear to be about three different kinds of situations for countries related to this infection - three different pictures. We have one group of countries - and these are countries in North America predominantly - in which we see community transmission which is established. We have seen a widespread occurrence of the virus within these countries, we have seen a significant numbers of people with laboratory-confirmed infection. These are countries such as Mexico, the United States and Canada. Within these countries, we are now seeing an evolving picture: in some of the places, activity has been going down. This is a clear in places like Mexico City and then in other places we have seen activity go up and come down, such as New York City and then go up again. Over the past week or so, there have been renewed outbreaks in schools occurring at a much larger scale than was occurring initially when the virus entered into the city.

In another group of countries and these are some of the countries in Europe and this also includes some of the countries in Asia, such as Japan, we have kind of a mixed picture. We have some people who are infected through travel or through close contact with people who have been travelling, or we also see outbreaks occurring in institutions such as schools, and we are also beginning to see other people who are getting infected with no clear risk factors. This is another group of countries that are in a little bit of a different epidemiologic situation. However, in these countries, and we remain in very close contact with them, talking with them on a daily basis, we still do not see large scale community outbreaks, we do not see large numbers of people going to hospitals with illness consistent with this infection.

We then have a third group of countries in which most of the infections are still largely limited to people who have been travelling or in contact with travellers. So right now, in different countries, in different places of the world, we have different epidemiological situations.

And then finally, of course, there are numbers of countries that have had no infections at all, so no travellers or nobody within the population who had been infected. In terms of the Southern Hemisphere, all of you have seen that there have been more countries which have reported some infections but we still do not see large scale outbreaks occurring in communities in any of the countries in the Southern Hemisphere.

The bottom line, in this mixed picture right now, is that it emphasizes again that we are in an evolving situation, countries are in different places, but this picture will continually change over the next few to several months. We expect to see that infection will probably continue to spread within countries and among the countries, and so I think that this is what we are thinking what will happen over the next period of time.

I think that there is a lot of speculation about what this means and I think it is very important to emphasize, as we have in the past, that when you are early in the spread of something like this around the world, you really have to keep an open mind. The picture is still evolving, we do not know what will happen later in the summer, we do not know what will happen in the fall time and as we have said on several occasions, we do not know what will happen if large outbreaks occur in some of the countries in the Southern Hemisphere.

For countries, this mixed picture has some very practical implications. And one of the implications is this: depending on the epidemiological situation where the focus of your surveillance might be, the focus of your control measures might be can differ. Again it emphasizes that in a very large world, that one size does not necessarily fit all. So in the countries with advanced spread of infection, it is now becoming very hard for them to count cases on a single basis. Some of the countries, such as the United States, are in fact moving away from large scale testing of cases and they will really be moving towards surveillance in which they are looking at: rates of illness, numbers of people appearing at doctors offices with illness with consistent with H1N1 infection, and they are really going to begin de-emphasizing, counting cases one by one.

This is a very practical issue, no country can keep up an intense amount of laboratory testing, all countries eventually run out of that capacity, but also the value of that information becomes less important. Once you know that it is there, it does make sense to move on to different kinds of surveillance. You can monitor what is going on in the country without over extending your resources. At the same time, what is important for these countries, is that when they do identify unusual occurrences - and there will probably be cases which are unusual, clinical cases, and there will probably be outbreaks, which are unusual – they still have to focus on those unusual cases and investigate them very intensively. This is how we are going to find out new patterns about this disease, this is how we are going to find out when the epidemiology is changing.

In those countries in which we see a mix of both travel-related cases and cases largely confined to institutions, such as schools, the important question then becomes: “Is the virus moving out into the community?” Again, we had mentioned that some of the countries are in this mix picture and it will be important for them to make sure that the surveillance systems are looking for that potential spread.

And then finally, for that larger group of countries, really the largest group of countries that either have no cases or have travel-related cases, the focus of surveillance is to detect whether new infections are coming into the country. I think that even in very technical matters, such as surveillance, this mix picture means that different countries are going to have to approach the situation differently. You will see that some countries will be looking at cases one way and some other countries will be looking for cases in another way, and it really is an adaptation to what is going on out there in the world, in what these countries are to be focusing on.

Over the past week in the time that we have not met, there has been a number of questions that have come up. One of these is related to vaccine, a lot of interest in where we are in the vaccine process. Just to go over some of the time frames and time expectations for this process, if we look at the development of vaccine - just the development of the vaccine as a product - by the end of this month, we are expecting and hopeful that the candidate viruses that can be sent to companies to be tested as vaccine viruses will be available. So we are hoping that these candidate viruses will be available to go to vaccine manufacturers pretty soon.

Once these vaccine manufacturers receive a candidate virus, they have to test the virus, see how it grows within their manufacturing systems. This still takes some weeks, they have to adjust and see if the growth of the virus is good, if the processing of the virus is good and so on. So this will add again some weeks of work on to that. If we put all of that together and sort of look at the kinds of work which has to be done, we are hopeful that by the end of June or beginning of July, this will be the time when commercial companies will be in the position of beginning to make H1N1 vaccine. So that is roughly the time frame that we are looking at over the next several weeks.

In addition to the processes, the technical processes for making the vaccine, there are some significant other processes going on in parallel. One of the big question coming up of course is that, once you can make the H1N1 vaccine should you make it, how much should you make, should you be making seasonal vaccine and so on, should you be making both and so these are difficult questions. As we have reported in some of the earlier press briefings, WHO has a process through its strategic advisory group known as SAGE to help answer some of these questions. This group has met already once, and one of the recommendations that they made is that during this time, while the vaccine development is going on for H1N1, that seasonal vaccine production should continue. This group is the group that we will ask to help advise on some of these other difficult issues, but we will hold off on making those decisions for a little while right now because what the decisions will reflect, such as the evolution of H1N1 activity, and really a process of trying to balance, what are the risks from seasonal influenza, first is the risk from this new H1N1 infection versus the risks of H5N1 infection, the avian flu out there.

Right now these are the kinds of questions and these are the risks that have to be balanced in order to decide how much vaccine should be made, which vaccine should be made. We are not at a time where we have to make these decisions yet, but that time will come and then these are some of the things that the committee will be asked to advise on, to think about and to wrestle with.

A third parallel process related to vaccines is very close contact between WHO and other public health agencies and with the private sector, with the vaccine manufacturers out there. One of the things we are simply trying to do is that in this kind of extraordinary situation, make sure that the public sector and the private sector are very well coordinated. So that they understand what are the priorities for the public health side and we understand what are the priorities and the realities for the private sector, for the manufacturers. This is where there has really been an extensive amount of discussion and collaborative work between vaccine manufacturers and public health. Earlier in this week, for example, the Secretary-General from the UN was here to address the CEOs of many of the influenza vaccine manufacturers to reach out as partners that this is a mutual endeavour.

In addition one of the things that we have tried to really get across is that from WHO's perspective to make sure that some vaccine is made available to the developing countries is a priority for WHO and these are some of the aspects of the discussions that we are holding with these companies.

A third issue that I wanted to talk about was the discussion about Phase 6. This was a very interesting week in terms of this issue. For those of you that were covering the World Health Assembly, I think that you know that the countries raised a question to WHO as to whether there could be flexibility in terms of the movement from Phase 5 to Phase 6. To put this request and to put this whole issue in context, I want to just step back for a second to make sure that everybody understands why did this even come up as an issue and what are the issues.

If we go back and look at the entire pandemic planning, pandemic preparedness process, which has been going on for the past few years, driven by concerns about avian influenza, these so-called pandemic Phases have been part of that planning process. This entire planning process was really initiated to help countries develop their capacities, develop their preparations as much as possible so that in the advent of a pandemic they would be better off than they would be without that process. So the pandemic Phases are really a planning tool for countries and a way to alert them that there is a situation that they need to be aware of and as a tool to make sure that they understand as we go into different Phases, there are different actions which should be considered by them and some of them which should be taken by them.

At the WHA, what the countries raised was a concern and they said that currently the criteria from going to 5 to 6 are based on geographical spread, and this is true. When you look at the criteria for Phase 5, you will see that it focuses on community transmission in two countries in one geographical region and if you look at the criteria from going to Phase 6, it focuses on community transmission in another country in another region of the world. It really reflects a sense that the virus is spreading out in the world and is becoming established in different countries. These were the criteria which were developed by the scientists advising and working with WHO over the past couple of years and in a sense they were developed to provide very clear criteria about the evolution of a potential pandemic.

But what the countries have said is that we are in a situation that is different than the spread of H5N1. In fact most of the cases that we are seeing right now are clinically mild and we are not having the kind of high death rates that we might expect if we were to see an H5N1 pandemic. Moreover. what the countries said is that we are in this mixed situation and we are concerned that if we go to Phase 6 the message to our populations will be: “You should be very afraid”, whereas in fact we think that it indicates that the virus is spreading out but the level of fear should not go up and there should not be an increase in anxiety. So, in taking these comments in from countries, what we did, what we thought about and what we discussed, is that right now, when we step back and say what is most important, the most important things are that, countries are as prepared as possible. This is a single most important action and this is a single biggest help that WHO can provide to countries.

And when we look and say: what are the actions that need to take place so that countries are as well off as they can be, in fact a number of these actions are already underway. Just to review for you quickly, I think that it is clear that all countries know that there is a new virus in the world which has the potential to cause a pandemic. I think that alert has been very successful and that is well-known. A second action taken by the countries and by WHO and a number of partners is to get information out to increase the communication. And this is well underway. There has probably been an unprecedented amount of information made available about the evolving picture, about the clinical findings, about scientific findings, than any other large scale outbreak in history.

A third action is that WHO asked countries to activate their Pandemic Preparedness Plans and overall when we look at the response to this situation compared to earlier outbreaks such as SARS, I think it is pretty clear that in fact the working on these plans and the activation of these plans has really led to remarkable level of communication and coordination among the countries. We have seen widespread sharing of viruses, we have seen immediate development work on vaccine start and so on and so these plans have been very helpful.

A fourth action that we have asked is for countries to take is appropriate control measures and again, you can see that a number of countries have done that, they have taken different actions to deal with infections going on in their country and to try to reduce that impact.

Finally there have been actions taken to increase the accessibility of important materials, such as vaccines and antiviral drugs. We have talked about this process about making vaccines available and this is underway at full scale speed. WHO has provided a number of antivirals to many of the poorest countries in the world, the vaccine manufacturers is stepping up its productions. These are the critical actions, these are the things which really matter in this situation.

So, what we did is take these country comments under advisement for flexibility and the other thing that really struck us is that in the response to this situation, we have on a very frequent basis made a lot of course adjustments. We have come back to you and talked in earlier press conferences about how the spread of this has causes to rethink things through and that this is a different situation than the spread of a virus like H5N1. There has been a lot of work to make these course corrections.

The large lesson that we have learnt here is that the response to these kinds of situations really have to be flexible, they cannot be rigid according to pre-made plans and I think that the comments from the countries reflect their same assessment of the situation. We have to have some level of flexibility here. Taking all of this into consideration at the here and now I cannot tell you what the new criteria for Phase 6 are, but I can tell you that what we are looking for and what we will be looking for is something which are events which signify a really substantial increase in risk of harm to people

This is the sense of what Phase 6 is meant to convey and this is what we will be focussing on. This has been a very interesting request from countries, it has led to very intense discussions about what is the appropriate response to pandemic influenza at this stage and given this evolution. This really reflects where we are, right now, at this time.

But before we move down or move to questions and I close down, again I want to emphasize one point which is really important. From the outset of this whole episode with the situation, we have really emphasized that there is much that we do not understand and that much that we expect will evolve. And this is really true: we have pointed out how we are not quite sure what is going to happen in the Southern Hemisphere, we are not quite sure what is going to happen in the fall time, we do have concerns about the illness having more significant effects in those more vulnerable populations. We do know from the past that the effect of the virus can change over time and the bottom line here is that we are trying to walk a very fine line between not raising panic but also not becoming complacent and this is the fine line that I think countries have to walk, this is the fine line that public health has to walk in terms of dealing with this kind of situation.

**DPA:** Just two questions, just for clarifications. One on the sharing of the vaccines, we are getting some mixed messages: on the one hand the CBC is saying that they are sharing, on the other hand the American delegation to the Assembly was concerned about intellectual property issues. How is this, are you hearing anything like this, that there are some concerns over intellectual property regarding the creation of a vaccine? And you also said that it will take until end of June in order from the vaccine to go into production. How long would you then estimate it would take for this to actually roll out at a capacity that you would be happy with?

**Dr Fukuda:** I am not quite sure which IP issues you are referring to. With this H1N1 vaccine, there are a lot of efforts right now to develop the vaccine as quickly as possible. In terms of the candidate viruses, there are two ways in which the candidate viruses can be made. One of them is using what is called "classical reassortment" which has no ties to intellectual property issues at all. And then there is another process called "genetic reassortment technique" which is tied to intellectual property issues held by a company. But the governments themselves are making no claims on intellectual property for the vaccine and the focus of the work being done in the US, as I understand, is really to develop pilot lot of vaccine try to get some of the information that everybody is looking for right now which is information on the immunogenicity of the new H1N1 vaccines and on the safety of this vaccines. Those studies really cannot begin until the vaccine itself is available and this is still going to have to wait for some weeks.

Now in terms how long will it take for the vaccine to be made available. Once a decision is made about how much vaccine can be made, one of the things we still do not understand right now is how much antigen you need in these vaccines in order for them to be immunogenic. We do not know whether it is the same that was done with the avian flu vaccines whether it would be closer to seasonal vaccines. So there are still some fundamental things that are not known until the trials can be started up.

**John Cohen, Science Magazine:** I think there is still a great deal of confusion about Phase 6. Are you saying that you are redefining Phase 6 to include severity? And let me put a fine point on it, if I might. Are you saying that if this were H5N1 at this moment, that the level of spread would lead you to declare Phase 6?

**Dr Fukuda:** I think that the fairest way to say this, because it is not clear to me, that severity is the only thing which would be considered in looking at what makes up Phase 6. I think that the larger concept is: what kinds of signals would be needed to tell you that the risk for people has really significantly gone up. This could be a change in the clinical severity. That could be a big impact. It could be other kinds of signals, such as what is the effect on countries in the Southern Hemisphere and so on, on a population level as opposed to a the clinical level for individuals. This is not decided yet but I would say that it is really an adjustment on our current concept of what is needed to go to Phase 6.

In terms of your other question about if this were H5N1 would we be at Phase 6, I think that even if it were H5N1, we would still be looking for clear evidence of widespread community outbreaks going on in countries in multiple regions. So this is still a situation that we have not seen yet. We know that there have been these outbreaks in schools, we know that there are some cases in which it is hard to find epidemiological links, but we have not seen the large scale kinds of outbreaks that we have seen in places such as Mexico and the United States and Canada. But I think that in many ways the distinction about going from Phase 5 to Phase 6 is important but really what is the most important, what is the real issue underneath here is, what is it that countries need to be doing now to be best prepared for what may come down the road and here we feel that many of the actions which should be taken are underway in many of the countries.

**John Zaracostis:** In follow-up to my colleague's question, you mention the possibility of vaccine production of H1N1 at the end of June or July. Would that be trial production or commercial level, because what about the human trials and the efficacy issues. Can you fast track them, we have heard that it takes 4-6 months before this process is done. Have you been able to short-circuit all that?

**Dr Fukuda:** At the end of this month - you know we talked about how the candidate viruses would become available and then it will take some time for the vaccine manufacturers to work with the viruses themselves. There are still some questions which are needed - to know what dosage level of the antigen, what is the potency level that would be needed to make an immunogenic vaccine and certainly safety will be very high on everybody's concerns. So there will need to be fast-tracking of some of these kinds of studies that will have to go on. These are some of the things which need to take place. At the same time, it may be possible to push ahead with some of the production of the vaccine. But it is certainly before you begin injecting people with vaccine, you want to know about some of these kinds of data and they will still have to be collected. They are not available right now.

**Maria Cheng, AP:** I have a couple of questions about Phase 6. Can you just clarify in light of these requests you have been getting from countries and the need for flexibility, is WHO right now re-writing its criteria for moving from Phase 5 to 6? And secondly, since we all know that influenza is so unpredictable, why were the old criteria so tied to H5N1, if all the experts knew it was possible there could be another strain that could cause a pandemic which would not be as deadly.

**Dr Fukuda:** I think that having finished the WHA today, we do have to sit down and think about the criteria. I think that the writing down of them is probably the easiest of the things to do. It is really to sit down and assess what sorts of indicators are needed to really go to Phase 6 in this kind of situation. In terms of the criteria themselves, I do not think that it is quite accurate that they were just tied to H5. But what really was the thinking during the process with the advisers was with the earlier versions of the criteria - the earlier versions really had a lot of things mixed into the criteria. They were quite confusing for people and difficult to interpret. A great deal of effort was put into making the criteria as clear and as understandable as possible, in a way that could be acted upon and measured as easily as possible. What has become clear is that it is not just the spread of the virus which is considered important by countries who really have to act upon the Phase changes, it is really the impact on the populations. It is this input that has to be taken in and considered in terms of the Phase 5 to Phase 6 change.

**Emtiaz Diab:** I want to ask about the number in the beginning and another question. You said there is 11168 cases and I think when quoted ten days ago, I asked the question, how many days the case infected to dies, I had been told in 6 days. That does mean those cases will die in 6 days? And I have another question about the pilgrim. Soon a big occasion in the Islamic world. Millions of people will go to the Saudi Arabia and that is a big danger. So are you thinking about that? We know that WHO negotiate at the moment with Saudi Arabia about this event and I would like to know your opinion about the danger of this amount of people who will be travelling.

**Dr Fukuda:** In terms of the first question, I want to emphasise that it is a small number of people that die from this infection. The vast majority of people develop in illness in which they will recover without needing to go to the hospital. Among those people who do develop a fatal illness, they generally end up going to the hospital in about a week or so, give and take some number of days. But the length of illness actually I do not think I can give you an average length of illness before people pass away. I don't know. Nikki is that available? The average length of illness before fatality?

**Nikki Shindo:** We only have data from hospitalized cases and that ranges from 1 day to 22 days. One of the cases was prolonged because of the ventilator support up to 30 to 40 days.

**Dr Fukuda:** So quite a wide range of days from the time that a person becomes infected to when they might die. And this again can depend on the kinds of complication that they develop. They do not necessarily die very quickly. Some of them may die quickly but others may die after some weeks after being in a hospital. In terms of your question about the Hajj, we are in discussions with the authorities in Saudi Arabia and there is recognition that the Hajj represents quite a unique event in which a very large number of people come together. This is under discussion with the authorities as to what steps might be taken to help reduce the chance of infection in that situation. I think that these discussions will continue over the next several weeks.

**Diab:** But what is your opinion as a specialist? As an expert?

**Dr Fukuda:** I think, it is a unique event. It is something that the health authorities in Saudi Arabia are very focussed on both this virus as well as the number of other infections in terms of how to protect the pilgrims who are coming to the Hajj. It is a difficult situation to think through and how to protect people in this kind of situation. But again we are under discussions with them about it.

**Helen Branswell:** I am going to ask two, if you don't mind. You mentioned the fact what is important at this point is that countries take the measure they need to be prepared. But I believe that some pandemic plans will have, or some pandemic vaccines contractors, will have rights on them that only taken when a pandemic is called. So if you do not move to 6 will countries and will vaccine makers make this vaccine in the scale that you are hoping they will make. That is my first question and my second question is, you said you were looking for widespread now, community spread of the disease. Some European countries including, I believe, the United Kingdom are using an algorithm or a testing protocol that specifically tell doctors not to test people if they do not have epidemiological link to a country where the disease is spreading like in Mexico and the United States or a confirmed or a probable case. With an algorithm like that you are never going to catch community spread. Is that appropriate at this point?

**Dr Fukuda:** In terms of the question about contracts, one of the lessons about the plans developed both by countries but also by WHO is that many of these plans were developed without any recent experience about pandemics. One of the key concept is that we have learned that we need to be flexible in their application. Certainly vaccine production can go ahead, whether there are contracts in place or not contracts in place, and I don't have significant concerns about that, I think it is really the evolving picture of the disease and decisions and recommendations made by the Advisory Groups to WHO and also to other national authorities which will really drive the vaccine process. I am not worried about the contracts in terms of slowing down vaccine production, but I think it is an important lesson to everybody in developing the plans they do need to be flexible.

In terms of the question about algorithms and finding cases, it is clear that what you are looking for at the beginning of an outbreak is different than you might be looking for later on the outbreak. In Europe much of the attention was spent on initially finding travel-related cases and so when you look at case definitions and so on being used by countries, it really reflect that emphasis. And more recently, number of questions have come up "Is that appropriate?" and what we have seen in these countries is that they are also greatly broadening the case definition so they are not restricted just to finding infections among travellers or close contacts. But another point that is important to make is that no matter what kind of case definitions you have out there, if you have large numbers of people who are getting sick, they will show up in hospitals and you will have these people being noticed at the same time. In a certain way it is probably a testament that if there are cases out there that are being missed, a lot of them are fairly mild cases and are not showing up in hospitals and are not showing up in physicians’ offices. It's good - it's certainly the right time for the surveillance efforts to broaden out and to detect what may be going on in communities but I also think if they were significant numbers of severely ill people, these would be detected in hospitals with or without any case definitions - it wouldn't be dependent on that.

**Hedayat Abdel Nabi, Kuwait News Agency**: Can I go back to your comment on the impact on the population which is affecting to move to Phase 6. Would the impact include for example high death rates, inability of hospitals to cope with the numbers, insufficient medical supplies, no availability of the vaccine, would all these compounded together would be factors affecting the population to move to Phase 6 regardless of the geographical spread?

**Dr Fukuda:** I think that these are some of the kinds of things that would look at for sure. To give you a good example, if the virus moves into the Southern Hemisphere and causes significant outbreaks in places such as Africa or South America and we see patterns which are different from what we are seeing in North America and that it appears clear that there is either a much more severe effect or there is a change in how the virus is behaving, these are the kinds of things which would signal that there is an increased risk for people getting harmed. And this is the kind of picture that we would be looking for, the kind of information that we would be looking for, and the kind of signal that countries would be expecting WHO to provide. That something is changing and that you really need to increase your state of alertness, your state of preparations, even to a higher level than it is now. I think it's a little bit early to give you exact words about what they might be, but I think that gives you the sense of what it is that would really be looked for to drive a message out that there is a significant increase in risk.

**Takuya Arai, Kyodo News:** I have two questions if I may. I understand that you decided to redefine the criteria from Phase 5 to Phase 6 after listening to the many countries' requests. On the other hand, I think you gave us a kind of impression that you changed the rule of the game in the middle of the game itself. Don't you think it does undermine the credibility of WHO's past decision? My second question is about the new criteria you are starting to consider. I think you don't have much time to do that. In what time line do you create the new criteria for Phase 6?

**Dr Fukuda:** First, we have to look and go back and say again "What is the intent of all of this?" Earlier on when I was talking - what is the value of these Phases, why are they even developed, why are they in place? Again, the big picture is that these kinds of tools are really there to help countries to prepare themselves, to provide alert, to get ready, to have some guidance that there is a time to take actions and then what sorts of actions should be taken. The criteria themselves developed under the guidance of a very large number of scientists from a very large number of countries over a significant period of time, led to the development of quite good criteria which are quite clear, but there is nothing like reality to really tell you whether something is working or not.

The purpose of WHO and the reason for WHO to exist is really to help people be protected. That is the bottom line and so rigidly adhering to something which is not proving to be useful in fact would not be very helpful to anybody. What we are trying to do here is to not change the rules but really to adapt to what is the situation, to really ask ourselves what is going to be most helpful for countries. I think the guidance provided by the countries in the WHA was extremely useful, very timely, and so we have taken that under advisement.

In terms of the timeline, I cannot give you an exact timeline. You know this is something which is obviously caught everybody's attention including our attention and we will think this through and we will try to get this right.

**Gabriela Sotomayor, Notimex**: It is just a clarification in this context could you define severity? Is it the dead people in the hospital?

**Dr Fukuda:** One of the interesting things about the discussions related to Phases had exactly to do with that issue: "What does severity mean?" Many people assume that severity simply mean how many people die versus people who are infected. When you talk about pandemic, people usually focus on: this many people die, this percentage of people die among the people who are infected and so on. In fact, I think that there are a lot of different aspects to criteria. That is one of them. How often people develop severe illness or how often people develop die from an infection. But there are other aspects. From earlier pandemic examples, we know that younger people are often affected at much higher rates than they normally would be from seasonal influenza. Besides that in some groups, such as pregnant women, back in 1980 pregnant women were about the highest risk groups who were dying from the pandemic influenza. It highlighted that there are certain groups that were at risk. Some times with other influenza infections we have seen that children develop unusual complications.

All of these things will certainly go into an assessment of what is severity. You know if you see certain groups of people who are disproportionately developing something quite serious then this would be important. But also on the level of populations, we know, what is the impact on the population itself. There are very large groups of people out there if you take many people who are malnourished, many people who have HIV infections, this is having a particular impact in the whole population on that group of people. Are things causing hospital and medical systems could not be able to function - these are different kinds of aspects of severity. It really depends on how you look at it. But I think all of these things go into to the ideas of severity.

# Transcript of virtual press conference with
# Gregory Hartl, WHO Spokesperson for Epidemic and Pandemic Diseases, and Dr Keiji Fukuda, Assistant Director-General ad Interim for Health Security and Environment, World Health Organization

## 26 May 2009

**Gregory Hartl:** Welcome to the WHO 5 o'clock virtual press briefing. Starting today, Tuesday 26 May, we will now hold these briefings once a week on Tuesdays at 5 o'clock. I would now like to hand over to Dr Keiji Fukuda.

**Dr Keiji Fukuda:** Thanks Gregory, again welcome everybody, thank you for coming. As usual, I will just go over a brief update and then I want to discuss one topic and we will throw it open for questions.

As of this morning, 6 o'clock in Geneva, we had 12 954 cases officially reported to WHO and these came from 46 countries. The issue that I wanted to talk about was something that we began discussing on Friday and this is about the Phase changes. Over the weekend there have been a lot of questions from some of you and still a number of issues that are of interest to people and I think it is worth talking about.

To go back, we are currently in pandemic alert Phase 5 and there has been a lot of discussion about what it is that would take us to pandemic alert Phase 6. As we talked about on Friday, one of the important things to remember about the Phases is that these were developed as planning tools to help countries in their efforts to prepare against pandemic influenza, so they came out with the *Pandemic Preparedness Guidance*. As you all know, over the last few years, we have been working with the development of these Guidelines in the shadow of avian influenza H5N1, which is a virus that has been extraordinarily lethal. This is really the background for the Phases.

The other important background that has occurred more recently is – before we had the World Health Assembly – there was a meeting in Asia, the ASEAN+3 meeting, and as part of that meeting, one of the requests from the meeting was for WHO to look at what the criteria were for going to Phase 6, and then to see whether the criteria should be adjusted. This was an official request coming out of that meeting. In addition, at the World Health Assembly there were a number of countries that also made a similar request to WHO: to take a look at the criteria and see whether they needed to be adjusted.

Again since these are tools – the Phases are tools really to help countries in their efforts to be ready for pandemic influenza – these were interventions that we took very seriously. This is one of the things that we talked about on Friday: about how we are now looking at, how we might adjust the Phases, a lot of questions about what would these adjustments be, why would we make such adjustments and so on. When we look at the current Phases – the definition for Phase 6 – right now you see it is very clear. It simply says that you have community level transmission in a country outside of the region in which we are seeing transmission going on right now at the community level. This would mean a country outside of North America and that is basically what the current criteria calls for. But the whole A(H1N1) – or the spread of this virus – has really highlighted the fact that this is a very different situation than with H5N1, or avian influenza.

Really, two of the things that we are looking at in depth after the interventions from the countries is: what level of community spread really indicates that you have spread in the community. In addition, there are a lot of questions from countries about severity – does the impact on the country, does the impact on people make a difference in terms of going up to the Phase. These are two of the issues we are really looking at right now.

In the current situation, we can clearly see that the A(H1N1) virus is spreading. We have seen that, in Europe, it has moved to a number of countries through travellers. There has been a lot of attention paid to some of the countries such as the UK, such as Spain, and then in Asia, we have seen that there has been a lot of attention paid to outbreaks going on in Japan. Then, more recently, we have seen increasing numbers of cases reported from some of the countries in the southern hemisphere but in relatively small numbers and often associated with travellers. Then we have the situation in the United States, Canada and Mexico where we really see what established community transmission really means. We have big outbreaks in big cities, we have virus spreading through the countries, spreading through provinces and spreading through states. Somewhat of a different situation than we see in any other country right now.

The other question that has come to WHO is: “Is severity important?” Of course severity is important. The whole reason why we take action against diseases is because they harm people. If diseases are relatively mild, like colds, then we take certain kinds of precautions, if diseases are very severe, such as avian influenza or HIV, then we take another level of precautions. Clearly severity is an important concept for public health and how we deal with these issues. But it is also clear that what is severe in one country is not necessarily severe in another country. This is one of the lessons that we have learned from many outbreaks, certainly one of the lessons from influenza.

In addition, when we talk about severity, it can mean different things to different people. For example, there is definitely clinical severity. If a person gets infected, do they just develop some symptoms and then get better, or do they end up in a hospital, do they die from the infection, or do they end up on a respirator? These are important questions at the clinical level. For countries, we can see that if there are a lot of sick people getting ill at the same time, hospital systems can be overrun, cities can ground to a halt for periods of time – and we saw that with SARS in some cities.

There is also severity at social level and national level, in addition to personal level. But capturing this is really a very difficult activity to do. How do you capture severity so that it is relevant for all countries, at the same time? This is a very difficult concept to capture. Nonetheless, the interventions from countries at both the ASEAN+3 meeting and the World Health Assembly were really things that should be taken into consideration. Currently what we are doing at WHO is trying to take a look at the interventions, trying to see what kinds of adjustments might be made to make sure that the definitions really meet the situation.

To do this, we will be asking a number of prominent scientists and people who really have a good perspective on the issues, to help us think this through. That is where we are right now in terms of the issues related to the pandemic Phases. I hope that it is clear. If it is not clear, please ask me any questions and I will try to clarify.

The other point that I wanted to make is that – and this is maybe the most important point of all – in all these discussions about the Phases, these are of course important questions, important issues, but the single most important question though is: “The public health actions that need to be taken, are they being taken right now?” That is more important than any definition, that is more important than any of the discussions. And here the Director-General has been really very adamant, pushing very hard all through the response over the past four weeks or so, that those actions which have to be taken, which should be taken, are taken. I think this is one of the other really important facets. That is what allows us to have this kind of discussion at this time because we are comfortable that the countries are doing the public health actions that they need to be taking right now. With that, let me throw it open to questions.

**Helen Branswell**: Could you please sort of flesh out a bit the process that you are going to use to reconfigure Phase 6. You said that you are going to be asking prominent scientists. Are you drawing them together in a meeting, is there a time frame, who will be involved, how are you going to do that please?

**Dr Fukuda:** What we will be doing is drawing together a group of scientists and public health people. We would like to do this relatively sooner than later, hopefully within the next few weeks. What we probably try to do is to convene this group of people by video conference and by telephone, to do this electronically which will be the quickest way to do it. We will try to get a group of scientists and public health people with a wide range of opinions and views on what is the right way to approach defining this kind of Phase, in this sort of situation.

**David Brown, The Washington Post:** I wish if you could address the question of why there seems to be so much reluctance on going to Phase 6. It is a very clear definition. The point was made, you know, long ago that it does not measure severity. What is to be lost by saying that it is community spreading, in the community and more than one place – which is obviously is – more than one region, we are going to go to Phase 6 and it is a mild Phase 6. Why not just bite the bullet?

**Dr Fukuda:** The answer to that is really almost another question which is: “What is to be gained by going to another Phase?" Again when we went from Phase 3 to 4, 4 to 5, the real gains for countries by doing that in terms of focussing attention, in terms of implementing actions, in terms of bringing in resources, and really focussing everybody’s attention on what had to be done. Right now, when we look at the request: “Why cannot WHO look at going to Phase 6” coming from the countries, there are couple of concerns here. One of them is that in many of the countries they do not see H1 activity going on, and in those countries with the few cases, things are relatively mild. And so, behind that question is the sense that many countries are already doing the things that are necessary right now to address the situation. But if you go and declare Phase 6 without very clear evidence that there is a sort of change in the global situation, it can lead to extra work for countries without much gain, it can lead to some level of panic, it can lead to some level of cynicism that something is being declared but which is not usefully producing something in terms of public health benefit and gain. These are some of the considerations that countries are wrestling with and conveying that to us and these are some of the things we are wrestling with. I guess that is the answer to your question.

**Mr Gregory Hart:** Dr Fukuda, thank you. Can I remind those who are listening on line that if they would like a question they should dial 01 on their keypad. So the next question from on line is Martin [unintelligible], Science Magazine. Go ahead please.

**Martin, Science Magazine:** I am a little bit confused. I think that WHO has always made it clear that epidemic could be mild and it did not have to be a devastating one. So why was not the whole issue of severity never integrated into an alert system? Is that just an oversight or it just did not occur to people? What was the thinking behind the system when it was designed?

**Dr Fukuda:** The Phases themselves as planning tools have been around for quite a long time. If you go back to the first *Pandemic Planning Guidance* which is several years ago, and the second version which I think came out in 2005, and you look at the version on the board now, you will see that they have evolved, and the way that they have evolved is that they have become in many ways simpler. The earlier versions of the pandemic preparedness Phases in fact incorporated a number of different concepts such as, the evolution of the viruses, transmission, severity, and so on. Much of the feedback, when we were going through the revision process was that the older pandemic Phases are too confusing. They have too many concepts in them, too many ideas in them and that they should be more straightforward and simpler and easier to apply. The most recent version of the pandemic Phases meet those criteria. They are much easier, they are simpler to understand, but like so many things, when you are really addressing a real situation as opposed to having discussions, what we have found is that they probably do not adequately capture all of the concerns of countries. And that is really what we are hearing now with the comments that came in over the past few days or so. That is what we now are trying to revisit and try to understand. How do we capture those things which are really important for countries at this time?

**Japan:** Can you tell me about the situation of the recommendation for the vaccine manufacturers? When will you issue the recommendation and in what process are you in?

**Dr Fukuda:** Currently we are in the process of developing the candidate viruses and these are the viruses that will be made available to the companies. Once the companies receive those viruses, they must test them out in their different processes to see how well they can make vaccines out of these candidate viruses. Then, once that process is over, the companies are in the position to begin to make A(H1N1) vaccines to this new virus. This is still some weeks away and so this is probably not going to be possible until about the end of June or the beginning of July – something in that time period. At that time, that we will need to begin making recommendations to the manufacturers about influenza vaccine. But we do not want to make recommendations too early because we are on a daily basis monitoring on how the situation is evolving, and depending on the situation, this would definitely have some impact on what the recommendations would be. The recommendations themselves will be deliberated by an advisory group the so-called SAGE Group, augmented by other people and other committees helping with those deliberations. That is where are right now. I do want to point out that once vaccine is made, then there till needs to be a number of studies which will be done to quickly get a sense of how immunogenic are the vaccines and to quickly take a look at safety issues and so on.

**Maria Cheng, AP:** I have sort of follow up to Helen's question earlier. This consultation that you mentioned that is going to take place in the next few weeks, does that essentially mean we are going to be in a holding pattern until that happens to determine whether or not we are going to switch Phases? When we are looking at the situation around the world, as you mentioned Japan has 350 cases and if the UK and other countries in Europe start reporting you might see community transmission. So what will you do when you hit that point?

**Dr Fukuda:** I am not sure that I can tell you exactly, but, for example if in another countries such as Japan or somewhere in Europe or somewhere in the southern hemisphere we begin to see activities which looks very much like Mexico or the United States – very large spread, very large outbreaks, with very large numbers of people then, you know, I think that this in and of itself could well be enough to take us up to pandemic Phase 6. But we will try to get the input in from the scientists to help us deliberate this through as quickly as we can. I cannot exactly foresee the events over the next, you know, few weeks or so.

**Donald McNeil:** I wanted to follow up on David Brown's question. He asked, I thought sensibly, why not bite the bullet and raise it to level 6 if it meets level 6. The response was: what is the gain, this could be the panic, this could be the cynicism, but isn't that the other danger is that if WHO changes its rules in the middle of the game, and appears to bend with the political pressure, that you create cynicism as well. If it looks like WHO will bend with the political pressure then it might do it with another public health crisis and there is a loss of confidence in WHO. There are other times when this question has been raised, for instance, when there might have been room for criticism with China doing during its silence in the early days of the SARS crisis, there might be criticism now with Indonesia for withholding viral samples. Isn't it important for WHO to maintain its credibility by sticking to its rules when it sets them?

**Dr Fukuda:** I think that there are clearly a number of issues in balance here, but among all of them, probably the single most important one is: "What actions can be taken, should be taken that are going to help people? What actions are going to make people safer, what actions are going to reduce the chances of harm?" When we go back and look at the current situation and also when we look at past situations that have been very difficult – and one of the most famous one was back in 1976 when we had the [unintelligible] swine flu influenza – when we go back to that event, one of the overall big lesson, perhaps the single biggest lesson from that whole episode is: "Take stock, take a look at what the reality is saying and do not put yourself in a hole and just leave yourself there". You need to take stock of actions over and over again. In this situation here, we have a situation where we have a virus spreading which is significantly different than avian influenza, significantly different than H5N1, we have a situation in which countries are saying ""We want you to take a look at these criteria because if you apply then in the wrong way, they may not help us. In fact, they may cause more difficulties."

When we look at those issues and when we look at the complexities of severity, and the complexities of defining trigger points for moving up, then it seems like it is a reasonable thing to take stock, take a look at the situation and say "really, what is the best way to proceed here." It would be possible to simply say, well, because something is written down, we need to just follow those, that is the most important principle. But really if you take the perspective that the bottom line is what is it that we are going to do which is going to be helpful for people, which is going to be helpful for countries, then I think, hopefully, it puts it more in perspective of why we are looking at this so seriously. Why we are considering what is important in moving up.

**Izumi, Japanese Television:** I would like to know about needs of developing countries for preparedness apart from medicines or vaccines, maybe they have special needs to be prepared.

**Dr Fukuda:** In most respects the needs of developing countries are exactly the same as they are for developed countries. In these kinds of situation what countries need and what they want is the ability to monitor what is going on in their countries: "Do we have the infection in that country, what is the level of the level of activity, are people getting more sick or things getting better?" So I think that these are basic capacities and to be able to do that, you know, you need laboratory capacities, you need epidemiologists, you need the training for those kinds of things, you need to have the ability to develop and apply control measures that are really appropriate for this situation. And many things like good communication skills and then in addition access to a variety of materials, such as vaccines and antivirals. In this respect, basically all countries are the same, all countries need the same things and they want the same things. What distinguishes the developing countries is that they often have fewer resources to get those and they have less of an ability to get access. Here, WHO and many partners in the developed countries have a big role to try to play in meeting some of those gaps in the developing countries. But there are a lot of basic capacities that all countries need, including the developing countries.

**Question:** This capacity building must take a long time and it must be very difficult. And people can get sick, they don't go to hospitals. Maybe they have much severe symptoms when they get to the hospitals. Maybe at the level of hospitals, they can have, I don't know something specific for these people?

**Dr Fukuda:** Yes, capacity building is really a very, very long-term activity. And it is not something that you can do in a few years. But on the other hand, this kind of activity has been going on for a long time. If you look at some areas which did not have laboratories in the past for influenza, there are now many more laboratories in the world that can diagnose influenza viruses. There has been a lot of experience over the last few years in terms of pandemic preparedness planning and this has been a huge help, both in the developing world as well as in the developed world. We see communications are much better, we see that countries immediately understand some of the issues about control measures, such as social distancing, isolation of patients. There has been a lot of discussion in planning – which is part of basic capacity building – which has gone on and which has been really very helpful. I think we are much better off now than we would have been if this had happened, five years ago or ten years ago. Nonetheless, certainly things like medical services in poor countries could be strengthened, they could be helped and these are clear gaps and we need to keep working on them.

**Richard Knox, NPR:** Thinking ahead, not too far, but over the summer and early fall as the vaccine production machinery cranks up and presumably will go forward to good significant degree and if we still have a lot of ambiguity about what the virus is doing and might do, I am wondering what you are planning to spell out in advance some of the criteria by which you would decide whether to deploy vaccine or not in the northern hemisphere fall, or whether you – especially in light of this past difficulty with phasing – would tentatively leave that as an ad hoc question

**Dr Fukuda:** No, it will not be left as an ad hoc question. What to do about vaccine production is clearly a critical component for responding to something like the current A(H1N1) situation. And particularly if things turn more severe rather in the southern hemisphere or in the fall time, but it is going to be a very difficult and complicated discussion if the situation remains as it does at the time when decisions have to be made. The way WHO typically works on this sort of situation, is that we do collect together or have advisory committee, SAGE committee is the group which usually advises WHO on immunization practices. In this instance we have augmented that group with additional members from other committees because the issues are particularly difficult. What we will do is to pose these questions to the committee and the committee will deliberate them and they will be asked to provide advice to the Director-General. This is how we will address this questions.

**Jon Cohen, Science magazine:** Leaving aside the Phase question, is it appropriate for the media to refer to this as a pandemic, and if it is not, what is your definition of the word "pandemic"?

**Dr Fukuda:** An easy way to think about pandemic – and actually a way I have some times described in the past – is to say: a pandemic is a global outbreak. Then you might ask yourself: "What is a global outbreak"? Global outbreak means that we see both spread of the agent – and in this case we see this new A(H1N1) virus to most parts of the world – and then we see disease activities in addition to the spread of the virus. Right now, it would be fair to say that we have an evolving situation in which a new influenza virus is clearly spreading, but it has not reached all parts of the world and it has not established community activity in all parts of the world. It is quite possible that it will continue to spread and it will establish itself in many other countries and multiple regions, at which time it will be fair to call it a pandemic at that point. But right now, we are really in the early part of the evolution of the spread of this virus and we will see where it goes.

**Steve, USA Today:** I want to ask about surveillance in Latin American countries. What sorts of mechanisms are in place and how confident are you that we have a clear picture of what is happening down there?

**Dr Fukuda:** Surveillance in Latin America and in the southern hemisphere, like it is in the northern hemisphere, is variable from country to country. So some countries have greater capacities, and others have fewer resources or do not have a good surveillance, but in general, we have enough good surveillance in enough countries and that if it is moving into a region, it will get detected. There are a number of surveillance systems that look at ill people going to hospitals, there are a number of good laboratories that can test specimens from these people and the bottom line is that, even in areas in which you do not have really good surveillance, when you start having large number of people becoming quite sick and going to hospitals, that gets noticed, independent of formal surveillance systems or not. The global awareness of the spread of this virus is pretty good. Countries are looking for it in their countries, and I am pretty confident that if the virus is moving out in a number of countries in the southern hemisphere that we will be able to pick it up.

**Betty, The Wall Street Journal:** Am wondering if the early tests all pan out well and things were going ahead. If you can provide something like a time-table, when do you think WHO and advisory committees will meet, when do you think some of these decisions will be made and when a vaccine likely will be ready given that it takes some time to produce?

**Dr Fukuda:** Just to go over the timeline that I mentioned a little while ago, we are now in the process of the most basic development of the vaccine, which is the development of the candidate virus and getting the candidate viruses and reagents to the vaccine manufacturer for them to test them out and to see whether they can develop vaccines out of the available candidate viruses. That group of activities will take us up probably through the end of June, beginning of July. That is the projected timeframe right now, and it is at that point that the companies will be in a position to begin developing vaccine. There will need to be still testing of the vaccine for immunogenicity, looking at safety and those sorts of issues, but from that point onwards it can go into production. Giving some indications from WHO in terms of A(H1N1) production will be important some time during the summer. Right now, I cannot be much more precise than that. We are in pretty close contact with the companies, trying to look at where they are, as well as being in close contact with our Collaborating Centres and the regulatory agencies to figure out where everybody is. And at some point we will need to reconvene the SAGE committee. They have already been convened once, they have provided one set of recommendations which are being acted upon now, but then they will have to be reconvened to help provide additional recommendations.

**Helen Branswell:** If you could explain something to us more clearly because I think there is a lot of confusion and I certainly share it. You are talking about the Phases as a tool and about how they are designed to be helpful to countries and how, actions are taken accordingly. But at the end of that scale, there is an event and there is a pandemic. Most of us are seeing that as a biological entity not a tool, not something that can be redefined. I am hoping that you could explain to us how you feel comfortable putting off the declaration of a pandemic at this point.

**Dr Fukuda:** If you look at the tools in the context in which they are provided in the overall *Pandemic Preparedness Guidance*, they do not stand alone. Where they are, they stand as a framework for countries to look at, in which there are a number of associated and recommended actions for countries to consider. When we look at the pandemic Phases, in a sense, what they do is to provide some sense of the spread of the virus, but they are clearly not an epidemiological description. If we were purely looking at the epidemiological description of the spread of these viruses, we could go over country by country and say where the spread is. They are also a tool that helps countries organize their thinking in terms of what sort of actions might be contemplated or might be acted upon at a certain point, and they also provide a certain kind of alert.

If you go from Phase 3 to Phase 4 to Phase 5 to Phase 6, it certainly conveys to countries that it is important for them to look at their plans, important for them to dust off certain actions and take certain actions. These are all public health tools, they are way of communicating with countries in a somewhat organized way about what their level of concern is, what their level of action should be. It is not primarily an epidemiological description. It is maybe a little bit confusing for people, but the intent of the Phases – and the Phases could have been worded in a number of different ways – they are plastic in that regard, they were really developed so that they could provide guidance to countries. If you are talking about natural laws, natural physical laws you cannot word them in too many ways, otherwise they are no longer a law, but these kind of things such as pandemic Phases are intended to help countries That is the fundamental issue that we are wrestling right now: how do we configure these tools so that it is most helpful for countries to deal with this current situation, and hopefully this will lessen some of the confusion.

**Gabriella Sotomayor, Notimex:** If the outbreak in other countries remains mild, but if the situation continues to evolve in North America or if it turns more severe for any reason, will WHO raise any kind of special alert for that particular zone, something like that?

**Dr Fukuda:** Right now, WHO has no specific plan to raise an alert for one region or another. The Phases, for example, are really intended to give alert to all countries around the world, a global alert about recommended actions and assessment of where we are. But clearly if the disease were to become significantly worse in one of the affected country, this is the information that we would get out to other countries as quickly as we could. This would clearly have implications for them about how they might think about what they should be doing in their countries. This is a little bit independent of Phases or alerts, but it would be critical information, and yes, we would definitely get it out to all countries as quickly as we could.

# Transcript of virtual press conference with Gregory Hartl, WHO Spokesperson for Epidemic and Pandemic Diseases, and Dr Keiji Fukuda, Assistant Director-General ad Interim for Health Security and Environment, World Health Organization

## 2 June 2009

**Gregory Hartl:** Good afternoon. This is the World Health Organization in Geneva, welcoming you to our 5 o'clock briefing weekly at this moment. So, Tuesday 5 o'clock Geneva time. I would like to welcome Dr Keiji Fukuda, the Assistant Director-General for Health Security and Environment here at WHO, who will make some opening remarks and then we will hand over to you all listening to ask questions. And now I hand over to Dr Keiji Fukuda.

**Dr Keiji Fukuda:** Thank you Gregory. Good afternoon, everybody. What I will do is follow the usual format where I give a very brief overview of where we are in terms of the epidemiological situation, and then there are some issues which I will cover and then we will throw it open for questions. In terms of the global situation update based on the officially reported information provided to WHO as of this morning, there are now 64 countries that have reported these new influenza A(H1N1) cases, the number of official laboratory-confirmed cases stands at 18 965, and this includes 117 people who have died with infection.

In terms of the overall situation, we continue to see three basic epidemiological patterns going on worldwide. The first one is that group of countries in which the spread of viruses advances and these are the countries in North America consisting of Mexico, the United States and Canada. In this area in which the spread of virus has been most advanced, we see activity going up in some locations and going down in other locations, then going up again in locations in which it previously went down. So we have a kind of mixed pattern going on in these countries in which activity waxes and wanes in certain locations, but overall there continues to be spread through these countries.

In a second group of countries we see that they appear to be in transition. These include countries in Europe, some countries in Asia, some countries in South America as well as Australia. In here, we are seeing larger numbers of cases occur with some I think early spread into communities but many of the infections related to institutions, to travellers but also a mixed pattern. We are seeing both travel-related cases and then some early community spread.

And then we have that group of countries in which there are limited numbers of cases and these appear to be related primarily to travellers, but sometimes to institutions, but without any real evidence of spread into communities. In terms of an overall assessment of the severity of what we are seeing, it is probably fair to call the situation something like “moderate” right now. We do have some hesitation in calling the situation mild for a couple of reasons.

First, what we know, is that the overall number of serious and fatal cases appears to be relatively limited compared to the number of known infections. However, based on the reports that we are getting from countries and based on the assessments of a number of experts, we also know that we really do not have a full handle on the number of people with serious illnesses. For example, yesterday on a conference call, we heard from some experts how they were seeing some people in hospitals with clinical symptoms which were a little bit different than what might be expected, who have A(H1N1) infection. We also know that we do not know the full number of people who are infected across the entire spectrum. So right now it appears that the number of serious illnesses appears relatively limited, but again we do not have a perfectly good handle on both the numerator and the denominator of what we are seeing.

The second thing is that we also know this infection can be fatal in a number of individuals and this includes both people who have some underlying medical conditions – it includes women who are pregnant – but it also includes people who are perfectly healthy, and so we do have some hesitation calling such an infection mild.

Finally, we do remain quite mindful that the future impact of this infection has yet to unfold, so we do not quite know what is going to happen in the Southern Hemisphere in the next few to several weeks, and we also do not know what the picture will look like in the fall time in the northern hemisphere.

Globally, we believe that we are at Phase 5 but are getting closer to Phase 6 and this is based on the following assessment: it is clear that the virus continues to spread internationally, we know that there are a number of countries who appear to be in transition moving from travel-related cases to more established community types of spread. Some of these countries are the countries that you have been following for quite a while, but they include countries such as the UK and Spain in Europe, Japan in Asia, Chile in South America and also Australia. However, we still are waiting for evidence of really wide spread community activity in these countries. I think it is fair to say that they are in transition and are not quite there yet, which is why we are not in Phase 6 yet.

Now, over the last several days we have had a number of discussions related to Phases and to the severity of illness. This is based on several different reasons including the input and requests from several different countries for WHO to look at this. Yesterday at WHO, we held a series of consultations with a significant number of experts – over 30 experts and public health staff coming from 23 countries spread across the globe – and the reason for these consultations was really to understand their perspectives and their concerns about a possible move from Phase 5 to Phase 6, and what considerations WHO should be mindful in doing so.

These discussions were very fruitful for WHO and provided a lot of excellent advice and guidance, and there is also consensus in a number of areas. First, the experts advised WHO to continue using the geographical spread as a basis for moving to a pandemic Phase 6. However, they also indicated that WHO should modify this kind of movement to Phase 6 with assessment of severity. In doing so, WHO should also provide more tailored guidance to countries, really to help them respond better to whatever the degree of severity of the situation is, in addition to just declaring that there is a Phase 6. Much of the discussion through the experts was over the matter of severity: how one makes such assessments with suggestions coming from the experts ranging from clinical assessments of illness up into economical impact and very large social measures.

Severity and the movement of Phase 6 have really been part of the pandemic planning process for the past few years in which a large number of other experts have taken part in. It is clear that assessing severity is a rather difficult job and there are some important considerations.

Severity is not just a quality of the virus and its ability to harm people, but it is a combination of that virulence but also the vulnerability of populations.

For example, how well off they are in terms of chronic conditions and so on, or perhaps poverty and malnourishment, as well as the resilience of populations: how well they are able to cope with new diseases or cope with diseases – for example, health care systems and so on. It is also clear that one of the tasks for WHO in providing severity assessments is to provide both global assessment, so everybody has a relatively good idea of what are we talking about, how does this situation compare with other situations, but also to provide guidance which is useful for countries and for sub-national public health authorities to make more local assessments.

The reason for this being important is that we know that severity is going to vary. It is going to vary by location, depending on those factors which I mentioned above but particularly the vulnerability of populations as well as the resilience of populations, and we also expect that severity could vary over time. For example, what we are seeing now may not be relevant for what we will be seeing later in the fall time. One of the tasks, one of the difficulties of doing this, is to provide such assessments so that they are simple to understand, so that they are accessible to everybody, so they are feasible. They can actually be measured by people at the local level as well as national level, and also internationally, and also to provide these assessments in a way that they can be used by the countries, by the media in terms of communicating information to the public, and really be understood by people.

We know that doing this is going to be quite a challenge. Based on the discussions that we had yesterday that lasted for several hours, WHO will be doing several things. One of the things that we will continue working on developing ways to assess severity and finalize these measures as soon as we can. One of the other things will be to provide more tailored guidance to help Member States so that they can better calibrate the actions. One of the things that we hope to do by providing this kind of tailored guidance is really to help reduce some of the more drastic actions, which may be uncalled for, but also to provide guidance to countries as to what steps they can take.

Some of the other things that we will be doing is trying to provide communications so that people understand what Phase 6 means, what the relationship of Phase and pandemic means in terms of severity and to convey across the spectrum that really all pandemics are not the same. Some pandemics can be milder, some pandemics can be more severe, and to try to make this a little bit clearer to people so they really understand what the situation is.

Finally, one other thing that we will be doing is running some of these actions and some of these issues by the International Health Regulations Emergency Committee. This is the same Committee that provides advice to the Director-General, or has provided advice to the Director-General in making the earlier phase declaration. So we will be running this kinds of information by the Emergency Committee to get their input and advice and guidance.

**Helen Branswell, Canadian Press:** A bit of a clarification on that question here. About the assessment of severity: I assume there will be some mechanism where you can change it over time, that if things start to unfold differently from the way there are going now, that you will be able to adjust that and adjust the guidance to countries. The question that I wanted to know is, now that we are starting to see spread in the southern hemisphere – I know that they are seeing it in South America and obviously in Australia – are we seeing that the virus is behaving any differently in terms of the variety and the toll it is taking on health care systems? Are you hearing reports of places where hospitals for instance are being taxed by the scale of the illness?

**Dr Fukuda:** Yes, we will build flexibility into the assessments of severity. One of the steps which we are entertaining, and this is again based partly on the thinking that when into the pandemic preparedness process, but also based on the guidance provided by the consultation yesterday, is to take a relatively straightforward approach, perhaps something like a three-point scale in which different levels of severity can be conveyed. The trick is not going to be so much coming up with the three levels of severity, but it is really how to do it in a way which can be implemented across a lot of different countries, but that is the basic plan. It is possible that, if we are in Phase 6, that we may see Phase 6 in which the severity is assessed to be relatively lower, and later on in the year have the severity assessment move up higher even though we are in same Phase.

In terms of the spread to the southern hemisphere, in general, it is fair to say that at the clinical level much of the reports that we are getting are pretty similar to the reports that we have gotten from the northern hemisphere. So that the illness that is being seen in Chile or the illness that is being seen in Australia, is similar to the reports of the northern hemisphere in which the majority of cases have been mild enough so that people certainly do not have to go to hospitals, but also instances in which we are seeing quite severe cases of the same kind of respiratory failure as we have seen in the northern hemisphere.

The other thing that is fair to say is that in some of the countries such as Australia, we have had similar reports to what we have seen in some of the locations up in the northern hemisphere, such as New York City, where there is a lot of activity going on. We have yet to see whether the sort of up and down pattern in the southern hemisphere is going to be the same as in the northern hemisphere, but there is probably a pretty good chance that this will be the case. Over all what we are seeing in the first few countries in the southern hemisphere is relatively similar to what we are seeing in the northern hemisphere.

**Frank Jordans, AP:** I would like to ask you about the ongoing spread of the disease around the world. You said it has now reached 64 countries, and some of the countries that you mentioned in the middle category such as Britain, seem to already be exporting cases. There were reports of students in Germany having picked it up in school in Britain. Can you tell us at what stage you believe Britain and Spain are right now, whether that disease is spreading from person-to-person and whether they are now exporters of the disease?

**Dr Fukuda:** These countries like some of the other countries are really in a kind of in-between stage. These countries are not detecting nor reporting a kind of very wide national activity that is being reported from the North American countries. On the other hand these are also countries in which infection has been detected for a significant period of time and are not just restricted to some travellers coming back. Without knowing exactly what is the situation in each of these countries, it is fair to point out that they are in a very different epidemiological situation than countries at other extremes. Where people get infected is of course very difficult to know. It may be that they pick up infection in a country that they are visiting, it may be that they pick it up at some transit point while they are travelling. The attribution of where people get infected for each individual is a little bit hard to tell. Nonetheless, having said that and having infection going on in these countries for some weeks, it would not be surprising if travellers can get infected in these countries.

**M. Walsh, BBC:** Can you give me some idea of the profile of the age group of the people who more likely to get A(H1N1) and those who are most likely to die from it. Is there a pattern emerging?

**Dr Fukuda:** The age profile has remained fairly consistent although we are getting some more information. The majority of people who have gotten infected are under 60 years of age. However, one thing that is becoming clear is that there are some people over 60 years of age who have also become infected. But still, the majority of people turn to be younger, so younger than 60 years of age. Among that group of people who have tended to develop serious illness, and by that we mean severe pneumonia that perhaps requires ventilator, or at least very severe pneumonia or people who have died from the infection. this tend to be younger to middle-age adults people who are in the age-range of 20 to 40 years old, but not just in that age group but, this is the overall epidemiological pattern of who has been getting infected and who has been developing the most severe manifestations.

**Hedayat Abdelnabi, Kuwait News Agency in Geneva:** I would like to ask confirmation about a case in Egypt. Did you get this confirmation? I do not get an update from the web site concerning the figures today?

**Dr Fukuda:** I will check on the figures. I am not sure, they should be updated but I do not quite know … sorry, I have just been told that the disease outbreak news goes up on Monday, Wednesday and Friday, so the figures will be updated on those days. In terms of the case in Egypt, no, I do not have any specific information on that case.

**John Cohen, Science Magazine:** I would like to make sure that I am actually understanding what has happened to it. It turns that WHO put on hold all the notion of geographical spread until you had this consultation and then changed it back to the original definition and now you are adding a severity scale that has yet to be determined to the phases. Is that right?

**Dr Fukuda:** Not quite. Let me go over this. It you look at the *Pandemic Preparedness Guidelines* which has been up there for quite a while, in fact you will see that there is discussion of Phases, 1 to 6, and there is also discussion of severity. Severity assessment of going to mild-moderate-severe, something in that range, and so adding severity to the pandemic Phases – or discussing it in terms of the pandemic Phases – is something which has been on the radar screen for quite a long time. Much of this work was really pioneered in the US for example, where they have a little bit more complex scale, but it is also something that at the global level, WHO and many countries thought as a good idea. This is worked on with the input of a lot of scientists for quite a long time.

But what did happen was that recently, at two large meetings – one of these was the ASEAN+3 Meeting held in Asia where many of the developing countries from that region – as well as a number of countries who came to the World Health Assembly had request WHO to look at the situation from going to Phase 5 to Phase 6, and to make sure that we are taking into consideration everything which ought to be considered, and not just going directly to making a Phase assessment. What that did was to really led us to go back and reassess what are the needs of countries if we go from one Phase to another, and particularly from Phase 5 to Phase 6. What in fact is needed by countries to make that kind of movement helpful to them? This really did take us back to looking at severity, looking at the Phase criteria, and then consulting with a large number of experts and also public health staff from a number of different countries.

What it did was to reinforce to us that what countries are saying is that the spread of this virus is really a phenomenon that nobody can stop and that nobody can get in the way of, but in order to provide tools and guidance to countries, which is really helpful to countries, that is not enough just to say that we are at a certain Phase and that the virus has spread to a certain extent. That kind of announcement really has to be accompanied by some indication of what the severity is and then some guidance to countries as to how they can modify their approaches to what is going on. What it really did was not change things so much, as really re-emphasize to us the importance of the additional information which has to go along with

Phase changes. I hope that this puts it in the context and give a little bit of historical context to the development.

**Helen Branswell**: I was wondering – back to what is happening in the southern hemisphere – in the northern hemisphere, when it first broke out we were seeing a mix of flu viruses and then in the last little while the seasonal flu strains have really kind of subsided and almost everything that has been seen at this point is the swine flu H1N1. What is the pattern you are seeing in the southern hemisphere? Is it blowing out the existing influenza A strains and B as well?

**Dr Fukuda**: As you mentioned, in the northern hemisphere when A(H1N1) appeared we were at the tail end of the normal influenza season and we saw a mix of influenza viruses and then, with the ending of the regular season, the northern hemisphere – or the influenza activity – has really been dominated by this new A(H1N1) virus. In the southern hemisphere we have some information coming from Chile that even though they are going into their regular influenza season, in fact virtually or most of the influenza viruses that they are seeing so far are the new influenza A(H1N1) viruses. They do have a number of influenza A viruses that have not been sub-typed but, importantly, they are seeing many fewer of the normal seasonal influenza viruses, and the majority of viruses are the new A(H1N1) virus. This is still early in the season in the southern hemisphere and we need to see whether this pattern holds up in other countries, but as you probably know from previous pandemics, this has been one of the patterns that has been seen with the earlier pandemics. And so I think that it bears very close watching.

**Burnett Muffy, Clinial Medical Technology:** I am just wondering. Canadian researchers from British Columbia CDC on May 6 reported the presence of H2N3 mutations that might explain the more intense incidence of the flu in Mexico, but there has been no further confirmation of the potential role of this virus. I am just wondering whether this virus or H2N3, how sure can we be that A(H1N1) is the only virus involved?

**Dr Fukuda:** Do you have the H2N3 virus strain? I think that you may be talking about H3N2 viruses, which would be a completely different matter. But to answer the broader part of your question, in these countries, an extensive amount of virological surveillance is done. For example, in the United States over 100 000 viruses – over 100 000 clinical specimens – typically get tested during the year for influenza viruses. Based on that testing, they identify what kinds of influenza viruses are circulating in the country. This – to varying degrees – is done in a number of other countries including Mexico. It is that kind of information which lets us know whether one virus or another virus is tending to predominate in that season, and that is how these questions get answered.

**Daniel, Web MD**: Dr Fukuda, almost nobody has your perspective on the current situation. I wonder how you personally see this outbreak developing over the next six months. What specific signs would indicate that this flu outbreak is becoming more worrisome or less worrisome than one would have expected?

**Dr Fukuda**: Well, like anyone who has worked in the field of influenza for any period of time, I would be very nervous to make any predictions about what will happen over the next six months, but I can tell you some of the things that we would be looking for.

Just to quickly review where we are right now, and to give you some basis for understanding what we would look for. We have this new influenza virus that we have not seen before. In the northern hemisphere, it is causing a significant amount of infections and disease in a time of the year in which you typically do not see influenza occurring. It is causing disease in age groups that are atypical for what you normally see with influenza and it is causing serious illness and some fatalities in an age group, and in a group of people who you do not frequently see such serious illnesses occurring. So we have an unusual situation right here.

As we move into the southern hemisphere, we are moving into a period of time in which that part of the world would be going through their regular influenza season. This is typically a time in which influenza viruses thrive. One thing that we will be looking for very carefully is whether the kinds of clinical illness that is typically seen with influenza is seen in the southern hemisphere or whether we see any unusual manifestations and particularly looking at things such as the age groups: do we see a repeat of the age groups being infected as in the northern hemisphere, or do we see some change in that pattern? Do we see some kind of change in the numbers of people developing serious illnesses and fatalities? Do we see changes in the virus itself? We expect the influenza virus to begin to drift and to develop some changes based on mutations, but does that really lead to any kind of changes in the behaviour of the virus, does it lead to any changes in terms of the antigenicity of the virus? We will be monitoring those kinds of characteristics very carefully. But the bottom line for all of this is really what is the impact on populations. Do we see disease populations which suggest that the virus is beginning to become more dangerous to people than it already is and that is the bottom line for all of the investigations. These are the kinds of things that we will be monitoring quite closely.

**Jon Cohen, Science Magazine**: You mentioned that at discussions you had that you talked about reducing drastic actions that are uncalled for. Could you specify some of the drastic actions that are uncalled for that you discussed?

**Dr Fukuda:** In this kind of situation we have not seen people getting infected from swine populations or from pork meat or things like that and yet initially on, a lot of the actions by some countries were really directed at embargoes, trade embargoes, some actions were directed at the culling of swine. Those things probably – certainly did not make people safer and may have caused some concern among the populations about the safety of either live animals or of the food that they were eating. Some of the things that we would like to do is to improve how we are able to communicate information, how we are able to provide guidance on what can be done in this situation, so that actions which are really unnecessary and potentially anxiety-provoking and unhelpful can really be modified or curtailed. Those are some of the things that we would like to see get done.

# Transcript of virtual press conference with Dick Thompson, Communications office, and Dr Keiji Fukuda, Assistant Director-General ad Interim for Health Security and Environment, World Health Organization

## 9 June 2009

**Dick Thompson:** Welcome to the WHO 5 o'clock virtual press briefing. Today’s briefing, Tuesday 9 June, is an update of influenza A(H1N1) situation with Dr Keiji Fukuda. We will start with a statement by Dr Fukuda and then we will take your questions. I would now like to hand over to Dr Keiji Fukuda.

**Dr Fukuda:** As usual with this briefing, I will do a quick update then there are some issues that I will highlight, and then I will throw it open to questions. As of today, which is 9 June 2009, the number of countries reporting laboratory-confirmed cases to WHO is 73 and the number of laboratory-confirmed cases reported to WHO is 26 563. This is a little bit more advanced than the numbers that are posted on the web right now. In these cases, this includes 249 deaths *(this was an error and was corrected later).*

In terms of what we are seeing right now, we continue to see the spread of this virus evolve and we continue to see new countries report the virus, and we continue to see evolution of activity within countries. As we have for the past several weeks, we continue to see ongoing infection occur within community in North America but we also have increasing reports of activity occurring in the Southern Hemisphere, particularly from South America and countries such as Chile, as well as from other countries, such as Australia. We know that Australia, for example, is seeing a great deal of activity in Victoria at the community level. In addition, similar to the activity in previous weeks, we continue to note that there is activity going on in Europe.

In terms of the virus, at this point, it is fair to say that the virus that we are seeing is relatively the same as the virus that we saw several weeks ago and there are no major changes to report at this time. The virus continues to be sensitive to oseltamavir and zanamivir, two antivirals drugs usually against this virus.

In terms of the epidemiology, we continue to see that the majority of infections are occurring in younger age groups, people younger than 60 and this is not exclusive. There are infections that are occurring in older people.

In terms of the clinical picture, what we are seeing in the southern hemisphere is similar to what has been reported from the northern hemisphere. That is, most of the people who have gotten infected have self-limiting illness which can be taken care of at home, or without specialized medical care and these people recover. However, as noted, there have been a number of serious cases – typically these are pneumonia cases or cases of respiratory failure sometimes requiring ventilators, sometimes ending in fatalities. Much of the earlier epidemiology of this situation was characterized by seeing infections occur in travellers, in institutions such as schools, sometimes military institutions and cruise ships. As we see the situation evolved, we know that outbreaks can occur in communities. And again this is the overall pattern that we are seeing. There are some examples, however, that we are paying very close attention to. For example, up in Canada, we know that there are reports of infections occurring in Inuit communities with a disproportionate number of serious cases occurring. These are observations of concern to us.

Now, there have been a number of questions which have been posed to WHO over the past weeks since we last had a press briefing, so what I would like to is go for a couple of them.

For example, one of the most basic questions that has come up is simply "What is a pandemic?" So here let me review what we are seeing and why we consider this situation which is potentially evolving into a pandemic. What we are seeing right now is the emergence of a new influenza virus that has not been previously known to infect people. What that means is that most people in the world really have very little background immunity to such a virus. We are seeing that this virus is spreading rapidly around the world, again the characteristics of previous pandemic viruses, and we are also seeing that the disease patterns caused by this virus are not what we see for seasonal influenza.

For example, in the northern hemisphere we have seen a great deal of activity occurring in the summer months, and we also have seen that most of the infections are occurring in younger people with the serious complications also occurring in the younger people. Again these are patterns which are not what we see with normal seasonal influenza. When you put all of these things together, what it really suggests is that we are in a situation which is really moving towards more or less a pandemic type of situation. The pandemic really refers to the fact that we are seeing the geographical spread of a virus that is causing this disease.

The second question that has come up is about the name of the virus. We know that the situation has been confusing. For example, right now, we know that there are H1N1 viruses which have been circulating in people for a number of years. This is a new H1N1 virus. And we also know that there had been H1N1 viruses which had been circulating in swine or in pigs for many years. And this has really led to a complicated situation of what you call a new virus. One of the primary concerns and one of the difficulties of naming such a new virus is to avoid adverse effects, or stigma associated with a virus name, especially if it causes some unwanted effects in either some sector or in some groups of people.

For example, we have seen in association with this outbreak concerns about food, concerns about pigs, which for our practical purposes are not warranted. Food has been perfectly safe, pork meat has not posed a danger for people, yet there has been a fair amount of anxiety associated with the virus originating in pigs and so to call this a swine flu virus is something that is really has a lot of potential for causing greater anxiety associated with eating pork or with these animals which is unwarranted. We have also seen that in past pandemics, the naming of viruses associated with geographical locations can often lead to a stigma and erroneous association that somehow the virus is more dangerous in an area, or perhaps associated with an area. This can manifest itself by travel restrictions or travel concerns that may not be warranted. And so again, in approaching the whole issue of naming the virus, these are some of the issues with which many people – not just WHO – but many people in scientific societies and different groups have been wrestling with. We hope to come up with names that are easy enough to remember, easy enough to use but really do not cause harm for either people or for sectors. This is one of the issues that has been wrestled with right now.

Another question that has come up is that "Are we in Phase 6 now, or why haven't we declare Phase 6 now?" In here I think I simply want to say that we know that the virus is spreading and we are now seeing that activity is picking up in a number of countries and this is, as I had mentioned before last week, we know that we are getting closer to probably a pandemic situation. But in the period of time since we last discussed this, I want you to know that WHO has been working extremely hard in terms of preparing countries, in terms of preparing populations for what a potential move to Phase 6 or pandemic would entail.

For example, there is work that is being undertaken right now so people understand really what does a pandemic mean, what does going to Phase 6 mean? Does this mean that we are seeing something really severe change? Does this mean that there is a need for drastic actions to be taken? And here I want to point out that by going to Phase 6, what this would mean is that spread of the virus has continued and that activity has become established in at least two regions of the world. It does not mean that the severity of the situation has increased and that people are getting seriously sick at higher numbers or higher rates than they are right now.

This is a very important point for countries to understand, for the media to understand, even if it is a little bit paradoxical. You would think that by going up scale would mean that the level of concern should go up, but really what the going up a scale would mean is that we are seeing greater spread of the virus. We are working with different groups to make sure these kinds of messages are understood and the difference between severity and geographical spread is understood. As I discussed last week, right at this time, we considered the situation and the impact on countries to be relatively moderate, and this is again a critical point. If there are some uncertainties, I hope you come back with questions on this.

One of the other things that is very important to understand and there has been a number questions about this, are changes over time. We are, as we have pointed out, I think a number of times in the past, at the beginning of the spread of this virus. Unless this virus suddenly disappears overnight, it is likely that the spread of this virus will continue and that activity will increase in some countries and go up and down in other countries. Now we know from past pandemics that in these kinds of situations, we can expect potential changes as we go through different populations and overtime. What does this mean? Well, it means that if we see spread of this virus into populations which are especially vulnerable, it means we may see more severe disease than we would see in populations which are relatively well off. I think the current reports coming from Canada about what has been seen in some of the Inuit villages is a good example of this. These are some of the potential changes that we know we could see as the virus moves through the southern hemisphere, different kinds of changes may happen overtime. If we look to the past, we see that how the outbreaks have behaved early on in a pandemic can be different than how the outbreaks occur later in the year, and months later. Again this whole concept that situation can change is important for everybody to understand because things may need to change, may need to be adapted, actions to be taken by countries and by people, and so on if situations change.

The last point that I will cover before we throw it open for questions is really another difficult issue. This simply has to do with uncertainties. Whenever we see a new disease, whenever we see any kind of large series of outbreaks caused by viruses that are new to the scene, we are in a period of great uncertainty. This is true of the current period right now. One of the difficulties for decision-makers and countries and public health institutions is that they need to make decisions, they need to move ahead even though many things are not so clear or are not known. To give you an example, right now, we know what the impact of the virus has been up to now in countries that are relatively developed, or in a number of other countries in which the number of infections has been relatively small.

But we do not know what the impact on the population would be as the numbers of infected people grow in populations, for example, in Africa or other continents where they may be large numbers of vulnerable people. We also do not know how this virus is going to evolve. It could become more mild over time, or it could become more severe over time, or it could stay pretty much as it is now. These are uncertainties that we have to take into account but we really do not know how that is going to go forward. Finally, we also do not know how in this global era in which there is so much media coverage, how populations will respond if we move to a pandemic situation, or a pandemic declaration.

For example, will the kinds of information being provided by countries and by media really be enough to address the anxieties of people or will people feel more anxious in this situation, and then how would they behave? These are really important considerations for public health authorities and for people who are working to make sure we have balanced an approach and a balanced response to handling the situation as possible. So at this current period right now, as we see the situation evolve, I can just summarize that WHO and its many partners, the Member States, the many public health institutions we are working with are really working to make sure that as the situation evolves we take all possible steps to reduce any adverse effects, any unwanted actions associated with uncertainties of a pandemic situation. With that let me stop and then let us throw it open for questions.

**David Brown, The Washington Post**: I am wondering if you can talk a little bit about the deaths and hospitalizations among people who do not have underlying medical risk situations or states that put them at higher risk? And I am wondering if there is any entity that is trying to sort of aggregate those serious cases that do not have underlying complications to try to see what might be going on, what obvious, or if there are any risk factors that can be elucidated that are not obvious ones?

**Dr Fukuda:** Even though the proportion of people dying who were previously healthy with those who are dying with some kinds of pre-existing medical conditions vary somewhat from location to location. It is probably fair to say that approximately half the people who have died from this H1N1 infection have been previously healthy people. This is one of the observations that has given us the most concern. I think that some weeks ago there was a lot of push by different groups to say that the pandemic was mild, that the disease was mild, but from the outset and from the reports coming from Mexico, we knew that a number of the deaths had taken place among younger people who were previously healthy. This is a kind of pattern that we have seen with the H5N1 virus, this is a pattern and a consequence that we have seen in earlier pandemics and so it did and it continues to give us a great deal of concern.

Among those people who have died – or previously healthy people who have died – from this viral infection, we know that some of them have died with clinical pictures consistent with respiratory failure, probably consistent with viral pneumonia. That is when the virus itself directly infects the lungs and causes infection, as opposed to secondary bacterial infections. But I do not think we know really why did those people die as opposed to the many other people who recovered, what kinds of underlying factors led to fatal illnesses. There are a number of institutions, a number of physicians who are looking at these cases and trying to understand if there anything that can be uncovered which provides some clues as to why some previously healthy people end up having fatal infections. Right now it is not possible to point out what may distinguish that group from other healthy people.

**Helen Branswell, the Canadian Press:** Dr Fukuda, at the beginning of your remarks you said that in Australia a great deal of activity is being seen in Victoria at the community level. Why then has the WHO not declared a pandemic, is there any doubt in your mind that this is a pandemic at this point?

**Dr Fukuda:** I think that we are really getting very close to that and I think that we again, as I elaborated in one of my points, one of the things that we are really focussing on right now, is to help countries, help institutions, help the media really understand what are pandemics, and really to provide as much information as possible so we reduce the chances for any adverse effects. Adverse effects would be panic, adverse effects would be misunderstandings that may lead to actions which in the end really just cause more anxiety among people and so on. Right now we are really working pretty hard to try to get these kinds of messages, this kind of information, out to people. Again I think that we are very mindful of what is going on in Australia and a number of other countries, and I will simply say that we are getting closer.

**Fergus Walsh, BBC London:** It is a follow up really on Helen's question which is, I've been speaking to infectious disease experts in Australia and they have said that given that there are now over 1000 cases in Victoria, that really the pandemic has started and they pointed out to me that they are actually stopping doing community level testing in Victoria because there are so many cases, they will now just be testing people to go into hospital and a couple of people out there rather wondering why you haven't declared a pandemic when this virus is really well established in the community and it sounded from your answer that in effect – and I don't mean this as a criticism at all – but it's a question of managing the media and managing the effects of when you go to Phase VI rather than the reality of the fact that we do have widespread outbreaks in at least two WHO Regions.

**Dr Fukuda:** I think that the declaration of Phase changes, the movement from one Phase to another, is not simply getting up in front of press cameras or making an announcement. It is again a way to prepare the world to deal with the situation, and so what is the situation? Well, it is the spread of this virus, the disease that it is causing. In doing so, there really is a great deal of work that has to be done. This is to prepare countries so that they have the kinds of information, the knowledge, the tools to handle increased numbers of people who may be sick, to handle the kinds of enquiries coming from their population about what to do, what does this mean. And it also means trying to make sure that all the steps that can be taken, are being taken. So right now we feel that the essential steps that should be taken are underway.

A lot of work is being done on communications, a lot of work is being done for example on vaccine development, a lot of work is being done on improving the antiviral supply, a lot of work is being done on developing clinical guidelines and providing updates on the science and so on, developing networks of calls where we get the clinical information and so on. All of this work is really what is needed in order for the world to deal with these kinds of situations. For WHO, the most important principle of all of this, is that the actions that we take, the announcements that we make, really are there to help people, to help countries, to make sure that we have as positive an effect as possible in making basically countries and populations as resilient as possible. This is not managing the media, this is not nuancing messages, this is really getting countries and organizations and populations ready so that they can handle and deal with this virus as well as possible. This requires a lot of effort and a lot of time and this is what is being done right now.

**Jonathan Lynn, Reuters, Geneva:** Dr Fukuda, I just wanted to check what you said at the very outset where you referred to 249 deaths and the figures of yesterday was only 139, that seems a very big jump, and I wanted to know if I had heard that correctly, and if so, what is the explanation for that. I had a second question as well but would you like to take that one first.

**Dr Fukuda:** Jonathan, let me actually ask for a verification on that and let me come back to you. Can you give me your second question.

**Jonathan Lynn, Reuters:** Is what you were saying about the reasons for going to level 6 and how it has to do with geographical spread and not severity, and I had the impression from what you were telling us last week and in other recent statements that the WHO is looking very much at severity and wants to incorporate that into the final declaration of a pandemic. Have I just misunderstood that, or has there been a change in your thinking in recent days.

**Dr Fukuda:** Let me again try to clarify this. When we talk about the declaration of the pandemic, if we go back a few weeks ago, we were talking about how WHO had been approached by a number of countries, again through meetings such as ASEAN and at the World Health Assembly, to look at all of the information that would be needed to move from Phase 5 up to Phase 6 – a declaration of a pandemic. What we consistently heard from those meetings and the countries, as well as from a round of consultations that were held with experts from many countries, from 23 countries, as well as public health experts, was that it was important for WHO to also explain the level of severity of the current situation with any announcement about a pandemic.

And the way to look at it is that we consider going out and explaining to people about the severity of the situation as an essential part of the announcement of a pandemic. However, the pandemic itself really does reflect the spread of the virus and the establishment of community level infections and activity in multiple regions. I hope that is clear. One part has to do with what does it actually mean that we have a pandemic but the severity is really critical information requested by everybody so that they can basically know how to take the news and what kinds of actions are appropriate to initiate in the countries. I hope that is clear.

**Bryan Walsh, Time Magazine:** Since it really seems as if the community level spread you are seeing in Australia, it does meet that definition for Phase 6, is there some threshold you are looking for in terms of this behind the scenes understanding or preparation. Are you looking for that once met you would feel more comfortable moving the definition up to Phase 6 What is it you are looking for when you are making these preparations because it seems as if your case numbers are not really the case here?

**Dr Fukuda:** Yes, it is not really strictly a matter of numbers. Of course, what we have stressed in the past that more important than the numbers themselves, is the establishment of spread in communities. And again, like you, we very clearly see what is going on in Australia and what we are doing is working very hard to make sure that the countries or partners, that everybody is in the best position as we get closer to a Phase declaration. As I responded to some of the earlier enquiries, I think it is fair to see that we are really getting close to this situation, but we are working very hard to make sure that everybody is as prepared as possible.

**Richard Knox, National Public Radio:** My connection got interrupted so I may be repeating what other people have asked and what you have already answered. I apologize. First, could you just characterize in somewhat more details what WHO is seeing in Australia and how it relates to your previous statements on the type of spread. You have for instance made a distinction before about spread that is within institutions, or expected kinds of exposures such as people in events versus wider community spread. I would just like to know how you see things in Australia. And then secondly – and other people have touched on this – but I'd just like to be as clear as we can. You know people do expect WHO to be clear and timely and they expect us to be able to explain what you are saying and I think we are all in an awkward situation at the moment. I wonder if you could give us a little bit more guidance on when you do expect to be ready to state what seems to be increasingly obvious.

**Dr Fukuda:** This is similar to some of the earlier questions. We were actually discussing the situation with Australia today and in Victoria, it is clear that they have been seeing outbreaks occur in both institutions such as schools, but they have also seen infections occurring in other people who are not students in these schools, and the situation has really evolved a lot over the past several days. In response to your question, we are getting really very close to knowing that we are in a pandemic situation or I think declaring that we are in a pandemic situation. Over the past week or so, when we had a discussion at the last press briefing, again I noted that we were getting closer and I think we are again much closer to that, but what we have been doing, what we have been focussing on, in the past week is really all of the preparations that we think are important for going to that kind of announcement by WHO.

It is not simply a matter of just going out and saying that we are in pandemic Phase 6, it is really a matter of making sure that countries are as prepared as possible, that they have the right tools to handle the situation, the right kinds of guidance, are able to address the concerns of the populations as well as possible, with the overall goal of WHO being that everybody – countries, their populations – are really as prepared as possible for knowing that we are in a pandemic situation. For example, one of the critical issues, is that we do not want people to over-panic if they hear that we are in a pandemic situation and that they understand that the current assessment of the situation is that this is a moderate level and that, for example, countries may have a variety of options to take in terms of responding to a pandemic in a moderate situation. Again, these are some of the things that we want to make sure, get out there that people are hearing them so that there is not really a blossoming of anxiety. This is one of our concerns, that countries are not adversely affected and their people are not adversely affected by going up to Phase 6.

**Jan Gold, DPA, Geneva:** I just wanted to understand if you can just specify what exactly would be an adverse reaction. You keep mentioning this word "handle", that governments have to handle. What exactly do you expect governments to do if and when apparently you declare Phase VI and what do you expect governments to do and what type of adverse reactions could possibly occur?

**Dr Fukuda:** First let me clarify the number that came up earlier. The number I gave you on the number of deaths was erroneous. The number of deaths is 140 so rather than the 249 – if you can make that correction – that is the number of reported deaths from this virus to WHO is 140. In terms of examples of adverse reaction that we would like to either see not occur or have them be reduced.

When we first announced about this virus and the situation, there were certain actions that were taken such as questioning the safety of pork, there was culling of pigs that went on, there were trade embargoes which were issued, there were concerns about travellers coming from certain areas, and there was concern over border closures or travel restrictions... a lot of those kinds of questions came up. These are the kinds of potential adverse facts that you can have if you go out without making sure that people understand the situation as well as possible.

In earlier outbreaks, in earlier pandemics, we have often seen that people who are in the category of being worried, but who were not particularly sick, have overrun hospitals, that sometimes the number of patients can lead to a dysfunction in the health system, simply because there are so many people going to emergency rooms and this can adversely affect people who in fact requires those emergency facilities. There is a potential number of consequences like that, that we would like to really make sure that the chances are minimized. These are some of the potential consequences that we are trying to reduce the chances for.

**Aline Gobert, CBC:** What is happening in the Indian community in Canada, in the First Nation community? Is it just a question of maybe means, the fact that those populations are very poor, or could it be some racial or some genes among First Nations in Canada that could be of the same far away family than the Mexican people who were sick also?

**Dr Fukuda:** What we can say is that when we look at past pandemics, we know that some groups of people, some populations have been particularly hit hard. For example, in some of the earlier pandemics, pregnant women have been a population that was hit very hard, much harder than most people, than most groups of people. We also know that outbreaks of regular influenza, in some communities, the effects can very severe. We have seen outbreaks of seasonal influenza take place in some African communities with the effect that significant numbers of children died, and significant numbers of older people died and in those instances, it is not really so clear what specific factors increase the disease and the severity in the populations: what is poverty, what is some other underlying disease, it is often not very clear.

In terms of the Inuit population, we know for example that some of the background level of chronic diseases can be higher in this population. These have occurred in villages that are relatively isolated although there are good health care services available. At this time we can say that we know a larger number than expected of young Inuit people did developed serious illnesses and had to get hospitalized. I do not think we know whether this reflects one characteristic, whether it reflects socio-economic factors, whether it reflects genetic factors, whether it reflects chronic underlying diseases. This is not possible to say at this time. We do know that in past pandemics, Inuit populations were very severely hit, and this is why these reports raise such concern to us. That is about the level of information that we have right now.

**Maria Chang, Associated Press:** I was wondering if you could clarify where WHO is in terms of redefining the criteria for Phase 6? You mentioned a couple of weeks ago that you were going to re-examine if there should be other things like severity, and now you sort of partly address that and I wonder where we stand with that and if there is going to be a new definition? And secondly am wondering if there is any concern at WHO that there may be community spread happening in certain countries in Europe, like say Britain, that are not reporting, are not testing for it. Do you think you are getting accurate information from these countries?

**Dr Fukuda:** In terms of redefining Phase 6, what we have decided to do is not so much "redefine" Phase 6, but to stay with the current criteria, really to augment the information provided when an announcement is made to Phase 6. Augmenting it really means coming out and explaining what we consider to be the severity of the pandemic, and also to come out with information for countries in terms of how to tailor them some of responses to the pandemic situation, which may differ from the pre-existing national plans. One of the issues that countries have been struggling with right now is that many of their existing pandemic plans where really based on a more severe scenario – the spread of the H5N1 virus – and some of the actions which their plans call for may be inappropriate. One of the things that we would like to do is, in addition to making any announcement about going to Phase 6, also discuss the severity of the situation, and also provide guidance to countries about how to modify and tailor the response actions to meet the current situation, and not to be so locked into by the pre-existing plans.

In terms of Europe, we know that the situation has been ongoing and continuing in some of the key countries. There has been a lot of attention being paid to the UK and to Spain over the past several weeks, both by the media as well as by the countries themselves, but in fact there is infection in a number of countries and reported by a number of countries in Europe. Our primary concern is not so much the numbers that are being reported. All of the countries without exception are working really quite hard to get a sense of what the situation in a country is and to report that information to WHO. It is really quite a different situation that we have seen in some of the other global and big outbreaks in the past. Countries are really working very hard to provide whatever information they can.

Our biggest concern is whether the recommendations, whether the actions being taken by countries should be underway to handle the situation right now, and so whether the information that is being provided by countries, whether the actions being taken to develop important tools such as vaccines are underway. That is really where at WHO our primary focus is on. Are the critical public health actions being undertaken? In here we feel pretty comfortable that what can be done is really being pushed forward right now.

# Transcript of statement by Margaret Chan, Director-General of the World Health Organization

## 11 June 2009

**Mr Gregory Hartl:** Good evening and welcome to this Press Conference being given by Dr Margaret Chan. Dr Chan will read a statement and then we will open the floor to questions. Dr Chan, thank you very much.

**Director-General:**

Ladies and gentlemen,

In late April, WHO announced the emergence of a novel influenza A virus. This particular H1N1 strain has not circulated previously in humans. The virus is entirely new, the virus is contagious, spreading easily from one person to another, and from one country to another. As of today, nearly 30 000 confirmed cases have been reported from 74 countries. This is only part of the picture with few exceptions countries with large numbers of cases are those with good surveillance and testing procedures in place.

Spread in several countries can no longer be traced to clearly-defined chains of human-to-human transmission. Further spread is considered inevitable. I have conferred with leading influenza experts, virologists, and public health officials. In line with procedures set out in the International Health Regulations, I have sought guidance and advice from an Emergency Committee established for this purpose.

On the basis of available evidence and these expert assessments of the evidence, the scientific criteria for an influenza pandemic have been met. I have therefore decided to raise the level of influenza pandemic alert from Phase 5 to Phase 6.

The world is now at the start of the 2009 influenza pandemic.

We are in the earliest days of the pandemic. The virus is spreading under a close and careful watch. No previous pandemic has been detected so early or watched so closely, in real-time, right at the very beginning. The world can now reap the benefits of investments, over the past five years, in pandemic preparedness. We have a head start. This places us in a strong position. But it also creates a demand for advice and reassurance in the midst of limited data and considerable scientific uncertainty.

Thanks to close monitoring, thorough investigations, and frank reporting from countries, we have some early snapshots depicting spread of the virus and the range of illness it can cause. We know, too, that this early, patchy picture can change very quickly. The virus writes the rules and this one, like all influenza viruses, can change the rules, without rhyme or reason, at any time.

Globally, we have good reason to believe that this pandemic, at least in its early days, will be of moderate severity as we know from experience severity can vary depending on many factors from one country to another. On present evidence, the overwhelming majority of patients experience mild symptoms and make a rapid and full recovery – often in the absence of any form of medical treatment.

Worldwide the number of deaths is small, each and everyone of these deaths is tragic. We have to brace ourselves to see more. However, we do not expect to see a sudden and dramatic jump in the number of severe or fatal infections.

We know that the novel H1N1 virus preferentially infects younger people. In nearly all areas with large and sustained outbreaks, the majority of cases have occurred in people under the age of 25 years. In some of these countries, around 2% of cases have developed severe illness, often with very rapid progression to life-threatening pneumonia. Most cases of severe and fatal infections have been in adults between the ages of 30 and 50 years.

This pattern is significantly different from that seen during epidemics of seasonal influenza, when most deaths occur in frail elderly people. Many, though not all, severe cases have occurred in people with underlying chronic conditions. Based on limited, preliminary data, conditions most frequently seen include: respiratory diseases – notably asthma – cardio-vascular disease, diabetes, autoimmune disorders, and obesity.

At the same time, it is important to note that around one third to half of the severe and fatal infections are occurring in previously healthy young and middle-aged people. Without question, pregnant women are at increased risk of complications. This heightened risk takes on added importance for a virus, like this one, that preferentially infects younger age groups.

Finally, and perhaps of greatest concern, we do not know how this virus will behave under conditions typically found in the developing world. To date, the vast majority of cases have been detected and investigated in comparatively well-off countries.

Let me underscore two of many reasons for this concern. First, more than 99% of maternal deaths – which are a marker of poor quality care during pregnancy and childbirth – occur in the developing world. Second, around 85% of the burden of chronic diseases is concentrated in low- and middle-income countries.

Although the pandemic appears to have moderate severity in comparatively well-off countries, it is prudent to anticipate a bleaker picture as the virus spreads to areas with limited resources, poor health care, and a high prevalence of underlying medical problems.

A characteristic feature of pandemics is their rapid spread to all parts of the world. In the previous century, this spread has typically taken around 6 to 9 months, even during times when most international travel was by ship or rail. Countries should prepare to see cases, or the further spread of cases, in the near future. Countries where outbreaks appear to have peaked should prepare for a second wave of infection.

Guidance on specific protective and precautionary measures has been sent to ministries of health in all countries. Countries with no or only a few cases should remain vigilant. Countries with widespread transmission should focus on the appropriate management of patients. The testing and investigation of patients should be limited, as such measures are resource-intensive and can very quickly strain capacities.

WHO has been in close dialogue with influenza vaccine manufacturers. I understand that production of vaccines for seasonal influenza will be completed soon, and that full capacity will be available to ensure the largest possible supply of pandemic vaccine in the months to come. Pending the availability of vaccines, several non-pharmaceutical interventions can confer some protection. WHO continues to recommend no restrictions on travel and no border closures.

Influenza pandemics, whether moderate or severe, are remarkable events because of the almost universal susceptibility of the world’s population to infection. We are all in this together, and we will all get through this, together.

## Questions

**G. Hartl**: Dr Chan will take questions and additionally may re-direct them to her staff if it is more appropriate.

**Question:** What do you expect countries to do differently as a result of this change?

**Director-General, Dr Chan**: With the announcement from Phase 5 to Phase 6, clearly, it sends an important message to countries that, irrespective of what state the epidemic is in their country, they must maintain continuous vigilance. As I said, the influenza virus is full of surprises. It is important, and depending on the state of infection in the country, if, say for instance, in a country that has not been reporting cases, they must be on the watch out for the arrival of the infection and start to prepare their people and also the health care system to deal with the arrival of the new disease. For example the United Kingdom, it is a country in transition that has already started very robust measures trying to contain the spread of the disease.

You can only do containment for some weeks and if you are seeing continuing spread of infection in the community, it is important that they move to mitigation measures, which is what they are doing. This is a smart way to conserve limited health manpower resources in the health system, medicines so that you can now focus attention on identifying patients, early treatment of patients, and making sure that vulnerable groups as described earlier get proper and timely treatment to prevent deaths.

**Question:** Does this increased spread step up the moral pressure on the developed countries to perhaps donate vaccines to the developing world that does not have such a good secondary health care system?

**Director-General, Dr Chan:** Calling a pandemic is also a signal to the international community. This is a time where the world's countries, rich or poor, big or small, must come together in the name of global solidarity to make sure that no countries because of poor resources, no countries' people should be left behind without help. And that is an excellent question. In that respect, I would like to advise you that the World Health Organization has been in contact with donor communities, development partners, resource-poor countries, and also drug companies as well as vaccine companies. I think this is my duty to get the views from the different groups of countries and see what WHO can do to make this a better world through equity, social justice and solidarity.

**Question:** What has changed and what made you take this decision today? In the case of Mexico, a lot of measures have already been taken to contain this virus, what more can be done?

**Director-General, Dr Chan**: First and foremost, you understood that I called a meeting by teleconference yesterday with a group of countries, trying to look at the evidence on the ground. And the evidence I am receiving, formal and informal, and after consultation with a group of countries, I made the decision to call the Emergency Committee set out under the International Health Regulations to examine the evidence available to us. It is a fact that all Member Countries as well as the experts on the Emergency Committee reviewed the evidence and there was consensus – unanimous decision – that we have indisputable evidence that we are at the beginning days of a global pandemic caused by a new H1N1 virus.

Now, your second question. Mexico, actually, in terms of its evolution of the outbreak in the country, it is coming to a steady state. They are only seeing sporadic cases and small outbreaks as reported to us this morning by the country so they have switched their measures. They should go into mitigation. Again as I said this virus is very unpredictable. In the event that Mexico is coming out of its first wave, it doesn't mean that Mexico should let down its guard. Mexico should continue to be prepared and keep up this vigilance because the virus can come back in a second wave. In other words, when you are over with the first wave, start preparing for the future.

**Question:** Dr Chan, in the run up to this announcement there was a lot of talk of WHO giving clear information on the severity of this virus. Could you elaborate a little bit on what “moderate” means and for the normal average person, should they be losing any sleep over this now that the pandemic has been declared?

**Director-General, Dr Chan:** This is one question that has been on the minds of many people. WHO now, based on available evidence, will look at of course a group of indicators, and some people call it a “basket of indicators”. For example, the number of deaths, the number of people getting seriously ill, look at the high-risk groups, and then also look at what is the impact of this new disease on countries. I would like perhaps later to ask Dr Keiji Fukuda to provide you with more details but I just want to make an important point on severity.

Severity can be taken in two dimensions: at the global level, that is what WHO is doing, we are reviewing the situation in different countries within the World Health Organization, and we give a global assessment. But we would encourage each country to look at their own situation to make a national assessment on severity; and in continental countries – big countries - they may even consider looking at what would be the severity at sub-national level.

**Dr Fukuda:** Just to amplify a little bit. Some of the things we looked at are the clinical features of the infection – how many people do develop serious illness and death and so on – and when we look at it that way, one of the things that we see clearly from most places is that most of the people develop illness that is self-limited. They do not need specialized medical care, they get better. And this is really what happens to the vast majority of people.

However, we also know that there have been a number of people who have developed serious illnesses ending up on respirators, having respiratory failure, and we also know a number of these serious cases have ended in death. And so, when we looked at that, we saw that while some of these are occurring in different age groups, really the predominant number of serious illnesses are taking place in younger people. So this is different from what we see with regular seasonal influenza. Moreover, we saw that about half of these take place in people who were previously healthy and do not have any pre-existing conditions.

Another thing we looked at when we spoke with the countries was really to ask them questions about how are the health systems coping, how are they able to take care of people and in general, there are places where the health systems clearly have been stressed, but in general the health systems have been able to cope. So by looking at a group of considerations like this, we felt that the level of assessment at this time appropriately is “moderate” but as the DG mentioned there are a couple of things that we want everybody to understand.

One is that severity can change over time. What we see now is not necessarily what we will see in a few months or later in the year. This is one important point. The second important point is that severity can reflect a number of different things: it is partly what the virus does, but it is partly the populations. So as the DG mentioned, we know that in the southern hemisphere there are populations which are younger, which have high levels of poverty in some areas, which have high levels of chronic diseases, and we know that if a virus that has a mild effect in a well-off population goes to such populations, sometimes it can be more severe than what we are seeing. We know that there can be variation from place to place and these are things that we are aware of now and that we are concerned about. What we are going to do is monitor this closely, we need to monitor it on a global level, we also know that local and national authorities need to monitor it at their level because what they see in one location may be different than in another location.

**Question:** You have mentioned that an important message you want to convey that we should help developing countries which are not prepared. So in what way can we help them and another question is in this pandemic situation, what are you going to recommend about the vaccine – the balance between the seasonal vaccine and the pandemic vaccine?

**Director-General, Dr Chan:** Thank you very much and yes, for countries, actually since day one of the emergence of this new virus, WHO has been working with our Collaborating Centres and with our development partners to provide technical support to our countries and that includes investigation on the ground, as in the case of Mexico for example, and we also sent laboratory diagnostic kits to the laboratories around the world to enhance their ability to make prompt and quick diagnoses, and we of course help to train their people and we will continue to do that. We also have – within the donation of antivirals – we have despatched to 121 countries in WHO so that resource-poor countries have a stock pile of antivirals for use, should the virus arrive at their doorsteps.

On the subject of vaccine, we have been in regular discussion with the vaccine manufacturers of the world, both in developed as well as developing countries. We were given to understand that they are close to the end of finishing their seasonal influenza vaccine production. So, they are prepared to start full-scale production of the H1N1 pandemic vaccine. Now, clearly, making the vaccine is a business decision and that is why some of them actually started earlier. There are vaccine companies that do not make seasonal influenza vaccine, so they have already started production, and there are also vaccine companies who have several plants, so some plants are making the seasonal vaccine and the other is moving getting ready to make the pandemic vaccine. So, it is a patchwork of different approaches, but at the end of the day, it is very clear now that WHO has made the announcement of Phase 6, we will get in touch with them urgently and assist them in any way we could, because we need to also bring together the regulatory authorities to look at what are some of the road blocks, so that we can help to fast track the registration so that vaccines that are safe, effective can be made available as soon as possible.

**Question:** I just wanted to clarify, where do we stand on the creation of a vaccine? How do we go down from here? In the sense that we are now at 6, we cannot go higher, how can we go lower?

**Director-General, Dr Chan:** Well, let me answer a couple of comments and then I invite my vaccine expert, Dr Marie-Paule Kieny, she would be able to give you more details on the vaccine question. You are absolutely correct, I mean at least there is equity now: no country has pandemic vaccine for the next few months because normally it takes about 4 to 6 months to make vaccine. For the next 3 months or so, definitely before September, no country would have vaccine. Even when we get into September and beyond, there will be limited supply of vaccine, and the challenge for the world is to look at who should get the vaccine and within a country, again which groups get the vaccine, so on that I turn over to Marie-Paule Kieny, to give more details on the vaccine.

**Dr Marie-Paule Kieny:** Yes, the vaccine manufacturers are standing ready to start producing since quite a number of weeks now. They have all of them have received the vaccine virus, which is the starting material, which allows them to go into large scale preparation. A very small number has been able to start, the other ones – we have discussed – will be starting next week or the week after that, so it is really the quick scaling up of production and we expect, as the Director-General said, to have the first doses of vaccine available somewhere in September. I cannot give you exact dates because it is a question of seeing how the preparation goes and how the regulatory authorities review the dossier. We must say also that at that period of time the number of doses of course will be very small and only by coming weeks and months there will be an accumulation of vaccine. In terms of recommendation for user vaccine, WHO is following the situation that is developing now in the southern hemisphere and also the situation of the northern hemisphere. When enough evidence is available in the coming weeks we will make policy recommendations on which group, which population should be prioritized for the use of the first doses of vaccine.

**Question:** As a follow-up question: how do we go down?

**Dr Keiji Fukuda:** In terms of how we go down, I think that there are a couple of parts to this. If we take a look at what is happening right now, we are in a period in which this new virus appeared and it is spreading around the world, and we expect this period in which the virus spreads to go on for some number of months. But at some point, it will become established in most of the countries around the world, which means that there will be a lot of people who will have gotten infected over the next one or two years, and then we will begin to see immunity build up in the population. We will see that this virus circulates and that it will really become much more like a regular seasonal influenza virus. At that point, all things which go up come down at some point, and so I think a lot of the heightened alert really switches over and makes a transition over to dealing with this as a long-term seasonal influenza virus. The really important point here is that, as we have tried to stress at the outset, when you are talking about pandemic influenza you are talking about a marathon, you are not talking about a sprint. We know that the virus is spreading, we know that we have to deal with this for a while and then we will adjust to it and countries – everybody will adjust to it.

**Question :** Dr Chan, are there any indications so far that the virus may be changing?

**Director-General, Dr Chan:** Based on the evidence that we have discussed, as late as yesterday, from all the countries with the highest number of cases, the virus is pretty “stable”, shall I put it in quotations, and the virus being analysed and looked at carefully in different countries, they look very, very similar, but you know you bring up an important point. We need to continue to track this virus and monitor it, and as and at the earliest sign of any change, we need to inform the world and we should never forget –as we are talking about H1N1 in Phase 6 – we still have H5N1 in Phase 3 and this is the first time we have two new viruses co-existing at different levels of the pandemic alert. This is an extremely unusual situation and that is why it is incumbent upon WHO working with all my Member States to stay vigilant and alert for the next year or two, or even beyond.

**Question:** I have a brief question but ahead of that, Dr Chan, as President of the UN correspondents, many of our members were dismayed at the selective briefing given by your agency earlier this afternoon, which created chaos in many newsrooms around the world. My question following this little protest, is that are Member States under the International Health Regulations (IHR) free to impose voluntarily if they feel like, travel bans and other quarantine measures, or do the International Health Regulations preclude that without notifying other Member States?

**Director-General, Dr Chan:** John, we apologize for that. The buck stops with me. Thank you. I take responsibility, do not give my staff a hard time.

You ask an extremely important question. At the early stage when we met with the Emergency Committee, based on the evidence, we made some recommendations. Clearly, no closure of border, no restrictions of travel, and also no trade ban and we make those recommendations. Recommendations are recommendations, and we did see that some countries are not following the recommendations coming from WHO under the IHR. But under the IHR, I have a duty: require them to provide me with the public health justification on taking those actions. And we have done so.

We keep chasing after all the countries and ask them to explain why they were doing what they were doing. And I am happy to say that things are getting better, but we must recognize that with a new disease, with a new threat, with a lot of uncertainty, it is not unusual to have a degree of overreaction and in some quarters they described it as panic. I think this is understandable, it is acceptable and we do need to give people the right kind of information to allow them to make that adjustment reaction. And we are seeing that this is being done very well and the countries are lifting all these bans that they have imposed in early phase. Of course we will continue to work with FAO, OIE and also WTO to impress upon the Member States of the countries that they should really follow our recommendations.

**Question :** I have two questions, first since this is the highest level we can get, can we assume that countries are free to break patents, for example for antivirals such as Tamiflu®. And secondly, what is your perception of what can be the impact of this declaration? For example, in the markets, or in the situation of the world economy that is already in recession. Do you predict that it can even make things worse, or what are your basic recommendations to the market itself?

**Director-General, Dr Chan:** Let me take the second question first. I do not have the crystal ball and I am not an economist. I would not delve into areas in which I have no core competencies. I hope you would accept that. The first question, again I am not exactly an expert on intellectual property but I can share with you what we have been seeing – since you mention Tamiflu®. Roche has offered sub-licence to many drug companies in some countries. In fact WHO has been inviting generic companies to come forward so that we could assist them with pre-qualification, so that generic medicine, generic oseltamivir, would be available as soon as possible. We are happy to say that we have done one pre-qualification for a company in India. At this point in time, they are available, both patented medicine as well as generic. I wish to say that Roche has made a donation to us – 5 million courses – and I have dispersed all of them to the countries, to 121 countries as I mentioned earlier. I am receiving a second donation in the quantity of 5.6 million doses, part of that is paediatric formulation and on receipt of that donation, over time, we will send them to other countries to make sure they have something in hand to deal with the situation.

**Question :** Basically my question was, if we leave aside the rather technical and scientific explanation for what the severity of this outbreak is, can you just explain for the average person how they should be thinking about this. Should they be really concerned, is this something that they can forget about for now, just some explanation that the average person can understand.

**Dr Fukuda:** Let me put it in perspective. This is one of those things that is good for people to know about. For example, it is good to know that there are different diseases and so on. But it is also really good for the average person to put it in perspective. If they develop a fever and cough, the vast chances is that they are going to do well. What is really important for them to know, if you are a mother, or if you are a family, that if you develop something like this, and then you develop something which indicates that there is something more serious going on, you know you have trouble breathing, or you have those kinds of difficulties, then to go seek medical care. I think that the average person should know about these things, their Government and information services may be providing important information, they are certainly going to read about it in the media, and to have a perspective on it, but definitely not to get overly anxious about it. It is like most things in life, understand it, put it in context, and then you go on with things.

# Transcript of virtual press conference with
# Dr Keiji Fukuda, Assistant Director-General ad Interim
# for Health Security and Environment,
# World Health Organization

## 7 July 2009

**Dick Thompson:** Welcome to the WHO virtual press conference for July 7 2009. This conference will last about 30 minutes. To begin with, Dr Fukuda will give us a brief update and then take some questions.

**Dr Keiji Fukuda:** Good afternoon everybody. What I would like to do is to start off with the usual situation update and then talk a little bit about surveillance recommendations and also talk a little bit about some of the oseltamavir-resistant viruses that we have seen in the past few weeks.

In terms of the current situation with the influenza H1N1 pandemic, we are now seeing that 137 countries, territories, and areas are reporting laboratory-confirmed cases to WHO. This includes 120 countries in that group. We have also received over 98 000 reports of laboratory-confirmed cases and over 440 deaths among those cases. As we go into this pandemic, it is important to point out that the situation continues to evolve quite rapidly. We are definitely in a period in which the situation is changing both globally as well as within many different countries.

Now in the next few days, WHO will be issuing some updated surveillance recommendations for countries and I just wanted to talk about these and explain the reason for it. Because the situation is evolving globally, we are now at a place in which changing some of the surveillance approaches probably makes a lot of sense for many countries. For countries which are having cases, we will be recommending that they begin to move away from trying to laboratory test all individual cases and really move towards larger national indicators of disease, for example following influenza-like illnesses, following pneumonia cases and so on. The reason for this is that because the numbers of cases have increased in so many countries, it is very hard to keep up and we now need to move to these kinds of indicators, to keep following along with the trend in the pandemic to see how activity is going, whether it is going up or down. It also will make it easier for countries in many ways because it will ease the burden on the laboratories and make testing much less of a chore than it has been for many of the countries.

Now in countries that do not have cases, however, we will be continuing to recommend that people who are suspected to have pandemic influenza be tested so that the presence of this virus can be confirmed in countries. And in addition, in all countries we will continue to stress that if you have unusual cases, so perhaps unusually severe cases, or perhaps unusual clusters of cases, or perhaps patients who are developing symptoms which have not been reported before, that these kinds of cases continue to be tested, to confirm that it is due to pandemic influenza. And then, that the cases in the clusters be investigated so we understand whether there are changes going on in the epidemiology and in the clinical picture of the illness. We will be putting up the updated guidance within the next few days and hopefully this will help with the monitoring globally for this pandemic.

A second issue that I wanted to talk about is that in the last two weeks or so, we have now heard about three oseltamivir-resistant viruses which have been isolated from persons in Denmark, in Japan and in Hong Kong. The isolation of these cases has raised some questions about what are the implications of this, and right now these examples of oseltamivir-resistance remain sporadic cases – we do not see any evidence of widespread movement of oseltamivir-resistant viruses. And so far, we have not heard of any additional viruses, including among close contacts of these persons.

There are a couple of important points to emphasize about these current oseltamivir-resistant viruses. In the first place, it is not unexpected that we will see some viruses that are resistant to this drug. This normally happens when you treat any infection with any drug. The important point here is that we are continually monitoring the situation to make sure that we are not seeing the start of any large-spread movement of such viruses. Again, I want to emphasize at this point we do not see this: we are just seeing sporadic cases but we will be monitoring the situation very closely. These viruses are also sensitive to the other neuraminidase inhibitor drug called zanamavir and then, these resistant viruses are also due to mutations – they do not represent any kind of mixture with the current seasonal influenza viruses so right now it looks like that these are spontaneous mutations in these patients.

Probably the single most important point about the oseltamivir-resistant cases is that, at this point, we are not recommending any clinical changes to the approach of treating patients and that is the most important point for physicians and countries to know.

The last thing I will mention is that – many of you know – that we are in the middle of an important meeting called SAGE, which is going on in Geneva. I left this meeting today – it continues on – and we will be discussing this meeting more in depth over the next few days, but will not be going into it in any detail today. So, with that, let me turn it over for any questions.

**Martin Ensureck:** I have a question about the naming of the virus. I read yesterday in a posting on ProMed that the World Health Organization, along with FAO and OIE, have chosen, once again, a new name and I wonder if you can explain to me when that decision was taken, by whom and why exactly this name, because already I have talked to some people who say it is not exactly a catchy name, it won't catch on the way that you would hope if you want to end the confusion about what the pandemic and the virus should be called?

**Dr Fukuda:** As you know, since the emergence of the pandemic, the name of the virus has been a difficult issue for many reasons. In the past, we have seen how the naming of viruses by location can stigmatize those locations and we have also seen in this and in other episodes where associating the virus with one animal species or another, can really cause both anxiety and then fears about food and in this particular instance, about pork.

So, in recognition of those issues, what WHO, FAO and OIE did, actually some weeks ago, was to get together several of the experts who work in these organizations and with many of the laboratory experts who work with these organizations, and then we had a meeting – a virtual meeting – in which these issues were discussed and one of the things that we wanted to do was make sure that any naming of the virus was scientifically accurate but also would avoid any kind of adverse reactions to the name or to minimize those as much as possible.

Based on those discussions, what the experts decided – calling this a pandemic H1N1/09 virus – was a good way to distinguish it from the current seasonal H1N1 viruses and to do so, in a way which was scientifically sound, but also would avoid some of the stigma associated with other options.

**Rebecca Smith, *The Daily Telegraph***: In the UK we have already moved from containment to mitigation and have stopped laboratory testing of all cases and moved to clinical diagnosis, but when that happened last week, we had some projections from officials and ministers that we could be seeing 100 000 cases per day in the UK by as early as next month. Now that is based on current trends of a doubling of the number of cases every week, but that would suggest that the pandemic would be over and done with probably by Christmas. Can you explain a little bit about how the pattern of disease is expected to continue once you move from containment to mitigation.

**Dr Fukuda**: Probably the most important concept to understand here is that depending where you are in the world – for example in the Southern Hemisphere where they are in the winter months and entering into their regular influenza season – they may see a pattern which is different from what is being seen in the Northern Hemisphere in countries like the UK, North America and so on. Now in the UK, as in many of the North American countries – Canada, Mexico and the United States – there has been quite widespread activity, or a lot of activity of this pandemic influenza virus, and right now it is at a typical point of the year where the activity should be pretty low, but the activity is quite high because it is a pandemic situation for these countries, and I think that it is likely that infections will continue in these countries.

However, I think it is a little bit hard to predict what the pattern will be for the remainder of the summer. It is possible that the UK and other countries in the Northern Hemisphere could continue to see fairly high levels of activity, but it is also quite possible that the levels of activity could go down because it is in the summer months. And then, again, it is a guess about what will happen in the fall and winter time, although it is more likely that activity will again pick up in the fall and winter time in the Northern Hemisphere countries. The same general perspective holds for the Southern Hemisphere countries where we can expect to see increased activity during the winter months but they may also see unusually high activity in the summer months. We are not positive about how any of this will develop over the next several months and so this is why keeping up with the surveillance is so important so we can monitor it closely.

**Maria Cheng Associated Press**: I have a couple of questions about the Tamiflu-[oseltamivir]-resistant viruses that have been picked up. I wondered if you might be any more concerned about the case that was detected in Hong Kong since that was apparently in a patient who had not been treated with oseltamivir, suggesting that maybe that the virus once it developed resistance might be … to spread and if you have any particular concerns about the potential reassorting with seasonal H1N1 which has shown a Tamiflu-[oseltamivir]-resistance.

**Dr Fukuda**: I think for that it is hard to know whether the virus isolated from the person in Hong Kong has any more implications than the viruses isolated from the two other people who were taking prophylactic doses of oseltamivir. If we look at the virus which was isolated from the person in Hong Kong, it has the same mutation as the resistant viruses isolated from the person in Japan and in Denmark. Again, it is not clear whether that mutation occurred spontaneously in the person who is infected in Hong Kong or whether they got that virus from somebody else who may have been taking oseltamivir. At this point, there is a great deal of attention to looking at the viruses coming out of the west coast area in which the person from Hong Kong was residing, but so far there are no other detections of resistant viruses in that area and in all three of the countries so far we have no evidence at all of any other resistant viruses. I think at this point it is not clear whether there is any differences in the implications of these three viruses.

In terms of the question about reassortment, I think that reassortment among influenza viruses is always a possibility and therefore always of concern. Again, I think that the bottom line here is that the major thing that we can do is to continue to monitor these viruses, continue to characterize them, look at their genetic composition and see if there is any evidence of reassortment with any of the other viruses, but again, so far, we do not see any such evidence.

**Marion Falco, CNN Atlanta**: My question may be a little basic but if you are not, and so forgive me for that, if you are not requiring testing in the countries that already have well established numbers of cases, then how are you distinguishing between seasonal flu and this particular flu. I mean how are you going to separate the numbers?

**Dr Fukuda**: It is not that we are recommending not doing any testing at all. In fact when the guidance comes out, what it will suggest is what countries are to do is tailor down their testing so that they are not trying to test everybody but certainly keeping up testing of some people for exactly the kinds of reasons that you bring up. When people get sick with an influenza-like illness it will be important for us to know whether is it caused by the pandemic virus or whether is caused by seasonal viruses. What we are indicating is that if you ratchet down the level of testing we will still be able to figure that out and so we do not need to test everybody for that, but we will continue to recommend some level of testing – at a lower level of people who continue to get sick.

**Mika Ruitch, CDF**: I have a question about the vaccine, you have not really mentioned anything. I understand that the meeting in Geneva is still going on about that but we have gone a really huge discussion here in Germany about it and I was wondering whether there is anything you can recommend to countries, whether to order or not already the vaccines.

**Dr Fukuda**: This is the SAGE meeting which is going on today and again, the meeting is actually still going on, so I think it is premature to make any reports on that meeting because it has not concluded . The meeting itself will end in recommendations which will go to the Director-General of WHO to look at, so if you can wait for a few days then we will be hearing more about the outcomes and recommendations of that meeting.

**Tom Mo, *Los Angeles Times:*** Can you give us a thumbnail description of what is going on in the Southern Hemisphere now?

**Dr Fukuda**: In the Southern Hemisphere we have seen activity occurring in a number of countries and similar to what we saw in the Northern Hemisphere, it varies a little bit from country to country. For example, a few weeks ago, Australia was reporting pandemic activity occurring quite heavily in some parts of Australia – in the Victoria area – whereas it was at lower levels in other parts of Australia for a while, then began picking up. In South America, there are viruses which have been isolated from most of the countries there, however much of the heaviest activity has occurred in Chile first and then more recently in Argentina. Again we are seeing a kind of mixed picture of activity in the Southern Hemisphere.

In Africa, if we go back a few weeks ago we would have said that there had been no viruses isolated from that continent but as of today 12 countries in the intervening period have reported detecting the virus. So, it is clearly spreading pretty quickly through the Southern Hemisphere; depending on the country you are seeing relatively lower levels of activity and then relatively higher levels of activity in some countries. Overall, I would still point out that for the Southern Hemisphere it is pretty early in their season so we still have a number of weeks to go through for that part of the world.

**Tala Dolachi,** ***Talk Radio Network News:*** You mentioned earlier that WHO is concerned about the surveillance systems and in particular looking at those national indicators. Of all the countries affected, are there any particular countries that WHO is focusing on now in terms of their inability to keep up to par with the national indicators?

**Dr Fukuda**: No, there is no particular country that we are looking at, and what we do focus on however is that if there are countries that are requesting help from WHO or from other Member States in terms of assistance to strengthen their surveillance, then we certainly give as much attention to those countries as possible. This has really paid off.

If we go back to the couple of years period before this pandemic occurred, for example there is a lot of discussions with the number of states in Africa and there has been actually a great deal of preparedness work which has gone on in that continent, and I can say that the number of laboratories which have the capacity to test for these viruses has really increased significantly in Africa. As of today, we have two new National Influenza Centres in Africa – one in Cameroon and one in Côte d'Ivoire - and so, although surveillance is definitely not optimal everywhere in the world, I would say that surveillance is definitely much better than it was three or four years ago. We will continue to try to build that capacity everywhere in the world where the countries are requesting help.

**Aileen Gobay, CBC Montreal:** I am sorry – the line was very bad and when you talked about the new name of the virus I did not catch it so can you repeat this information for me please?

**Dr Fukuda**: We are calling it the pandemic H1N1/09 virus. This refers to the fact that it is a pandemic influenza virus. If you look at the scientific subtype, it is an H1N1 virus, and the 09 refers to the current time period. Hopefully this will help to distinguish this virus from the seasonal H1N1 viruses.

**Gabriella Sotomayor, Mexican Press Agency:** How severe are the cases who receive the Tamiflu [oseltamavir]? And of all the cases in Argentina, in general terms, are those cases more severe like in the beginning in Mexico or is it moderate?

**Dr Fukuda:** I believe all three people have now recovered completely: They have uncomplicated illness. In terms of your second question, it is a little bit difficult for me to answer that so precisely. We know that in Argentina, for example, that most of the cases, as everywhere, have been uncomplicated influenza cases that is to say have not required special medical attention, or special medical care. However it is also true that in the last few weeks, there have been a number of serious cases hospitalizations and some deaths reported. I am sorry but I do not have exact numbers on my fingertips right now. It is a mixed picture similar to many other countries, I cannot tell you whether it is specifically like Mexico was at the beginning of the pandemic.

**John Zeracostas:** I wonder if you could give us a little bit of a bird's eye view on the three-day modelling experts meeting here in Geneva on how they project the spread of this pandemic in the short and medium term?

**Dr Fukuda:** The purpose of that meeting which was held last week, was to further building up a WHO network in which modellers from around the world could work together on some of these pandemic problems, and other infectious disease problems. The meeting brought together over 20 different experts from most of the continents around the world, and what they discussed was some of the preliminary findings of some of the projects that they have been working on, some better ways in which modelling groups around the world could work together – could operationally be linked more closely together – and those were the primary areas of focus of that meeting. I'm sorry I cannot report on any specific project from that meeting, I was not there in attendance.

**Lisa S________, *The Telegraph News:*** I wanted to get back to you about the Southern Hemisphere situation, thanks for the snapshot on that. I wanted to see if you also are able to tell how the seasonal flu is doing there, how the pandemic flu is competing against it, what trends you are seeing, if you are able to tell at this point in the flu season, I know you said it was early, but just wondering what you are seeing so far?

**Dr Fukuda:** The countries are seeing a mixed picture depending on the country. For example, in Chile, it was just reported that over 99% of their influenza viruses are the new pandemic H1N1 virus. By contrast, in Australia, they see more of a mixed picture, where they are seeing both the pandemic H1N1 virus but they are also seeing a seasonal H3N2 virus that circulates there. Then, if we go down to South Africa, right now the seasonal influenza viruses are much more predominant than the pandemic influenza viruses. In the Southern Hemisphere, it is fair to say that there is a mixed picture. In another month or so, we will have again a much clearer picture about how the pandemic virus is spreading in the Southern Hemisphere and whether it is beginning to crowd out the seasonal influenza viruses in many countries or in just some countries.

# Transcript of virtual press conference with Gregory Hartl, WHO Spokesperson for Global Alert and Response and Dr Marie-Paule Kieny, Director of the Initiative for Vaccine Research, World Health Organization

**13 July 2009**

**Mr Gregory Hartl:** This is WHO Headquarters in Geneva. We welcome you all to this virtual press briefing today. My name is Gregory Hartl and with us today is Dr Marie-Paule Kieny, the Director of the Initiative for Vaccine Research at WHO Headquarters who will make a few opening remarks about the results of the SAGE Committee meeting of last week and their recommendations and then we will open the floor to questions. As always, please, if you have a question to ask please dial 01 to get into the queue to ask the question and state your name and organization. Dr Kieny over to you:

**Dr Marie-Paule Kieny:** Thank you very much Gregory. It is a pleasure to be with you again to give you this update on the recommendation of the SAGE on H1N1 vaccine and vaccination. The SAGE is the Strategy Advisory Group of Experts, that is the highest level of advisory body in WHO on immunization matters and they met last week on 7 July to be updated about the epidemiological status and the clinical status of H1N1 as well as being provided with an update on expected vaccine availability. They also reviewed the status of production of the current seasonal epidemic vaccine. As you know we are coming to the end of the production campaign for the vaccine which is meant to be used to fight seasonal epidemic of influenza in the northern hemisphere starting this fall and they also met to review various vaccine options that would be available both for seasonal immunization and for H1N1, and to make recommendations to the Director-General. The SAGE, which was helped by a number of experts and also by another committee that we have established in May, which is more specific about the expertise in the area of influenza, so the group together came together with recommendations that were endorsed by the Director-General on Friday. In general these recommendations take into consideration as I said the epidemiology, the severity of the disease, the expected availability of H1N1 vaccine and have come up with a number of recommendations. I will be very happy to detail them following questions but just to give you an idea of how they go. First, the Committee recognized that the H1N1 pandemic is unstoppable and therefore that all countries will need to have access to vaccines. Second, the Committee also recognized, really acknowledged the fact that different countries have different epidemiological and other situations and therefore that the countries themselves will have to take decisions that are best adapted to their own national situation but in terms of giving indicative consideration and guidance to countries, SAGE recommended first that healthcare workers should be immunized in all countries in order to maintain functional health systems as the pandemic evolves. So there are several reasons to protect health workers when they put themselves at risk, when they care for patients; the other one is because they need to remain in good health condition to care for pandemic influenza sick people and the third is because during the time of a pandemic people will continue to be ill with other diseases and these diseases will also need to be taken care of. Second the SAGE considered the gravity of the disease in various groups and considered that countries may have different strategies when they implement immunization campaigns.  So the first one would be to try to stop transmission and if you want to stop transmission as much as you can, and this may still be possible, in certain settings at least to mitigate transmission, you target different population groups, and if you just want to have other objectives: So the first objective is to reduce transmission as much as possible.  Another objective might be to reduce morbidity and mortality and the third objective, but there is no priority in order, would be as I said, to protect the health care system.  In view of these three objectives countries might have, and depending on their own decision, they may consider immunization of several different groups - one of them being pregnant women e.g. as I am sure you have followed in the news, pregnant women are at elevated risk of severe diseases and death; other groups would be anybody over 6 months of age with chronic health conditions and these induced variety of conditions which are putting more people more at risk from having severe illness. This could be chronic respiratory disease - it could be obesity which has been now shown as being a risk factor. Another group to be considered would be healthy adults of over 15 years of age and less than 49 which have been shown also to be surprisingly, although were healthy, at risk of death.  Yet another group would be healthy children and this is mainly to reduce transmission as we discussed because children are amplifiers of infection because they meet in groups.  Yet another group would be healthy elderly adults and all country conditions need to be taken into consideration when countries make decisions.

The SAGE also then, to further go into decision and in going out with recommendation for target groups, considered the safety of adjuvant vaccines and they noted that there was, so far, no concern of the safety of vaccine adjuvanted with the new oil-in-water adjuvants but that it was urgent to collect safety data in groups for which safety data is not available in numbers for the time being.  They also noted that because these vaccines are novel, use for some of them, a very good post marketing surveillance and pharmaco- vigilance has to be implemented when the vaccine is deployed and that international cooperation is requested to have results of any signal that some vaccine might not be safe, which we don't expect but you never know, be shared with the international community as soon as possible. Finally, they considered recommendations on seasonal influenza vaccination.  They were informed that the campaign for preparation of seasonal vaccine for the northern hemisphere were close to completion with more than 90% of production being finalized by end of July and therefore considered that there was no need to recommend a switch from seasonal to H1N1 vaccine.  They also considered that at the current time there would be no change in recommendation of WHO  for the seasonal vaccine for the next season for the northern hemisphere, that preparations should continue for this immunization as if there would not have been a pandemic. So these are the main messages and I will be most happy to answer your questions.

**Mr Gregory Hartl:**   Dr Kieny, thank you very much.  Before we go to questions can I remind journalists that the audio file and transcript will be available shortly afterwards as usual on the WHO website.  In addition, a web update outlining in summary, the conclusions of the SAGE meeting will be posted shortly.  Once again, journalists who want to ask questions please press 01 on their keypad.

**Fergus Walsh, BBC:** Regarding the southern hemisphere can you tell me were there any decision made to ask companies like CSL and Sanofi Pasteur who will, in the general run of things, make seasonal flu vaccine for the southern hemisphere, they would  normally expect in the autumn, to get the strain from you and do that. Whether or not you are planning to allow next winter's southern hemisphere seasonal flu vaccine to go ahead or whether you consider the pandemic is serious enough and that they should just concentrate on the pandemic vaccine and secondly, when would you expect the first doses of pandemic vaccine from cell culture to arrive?

**Dr Marie-Paule Kieny:** In terms of southern hemisphere, this was of course discussed and SAGE considered that it was too early to make recommendations on the upcoming production of the southern hemisphere vaccine. Indeed, the southern hemisphere seasonal epidemic has started and now we are in the middle of it. It seems that there is still a significant proportion or number of cases which are caused notably by H3N2, one of the seasonal strains. There really needs to be more data accumulated on what is circulating in terms of the new virus or the traditional H1, H3 and B strains. So we expect that all these data, much more data and evidence will be available in September when traditionally WHO will hold its meeting to determine which strain should be put into the seasonal vaccine and by that time we hope that we will be able to be more explicit in giving recommendations in one directions or another. I still need to note that seasonal influenza is a severe disease in certain population groups, like the elderly or the very the young and nobody would want to have an epidemic of severe and preventable seasonal epidemic in nursing homes when winter comes in the southern hemisphere. So this is something which is watched very carefully but it is too early to give any recommendations.

On when the first doses of pandemic vaccine made from cell culture would be available, there are already vaccine doses available. They are produced but they are by no means ready to be licensed yet. So both the doses are available for clinical trials, from both manufacturers who have been making vaccines from cell cultures but also coming very soon or are already there, as you may know, from manufacturers who are making vaccines from egg products. Notably, CSL in the southern hemisphere has really been rushing to prepare for clinical trials. So when we hear that vaccine is available already, certainly, yes, vaccine has been produced but it is still an experimental vaccine awaiting results of both pharmaceutical characterization to be licensed as well as upon request of regulatory authority clinical trials.

**Helen Branswell, Canadian Press:** If I could ask 2 questions. The first is a clarification. Dr Kieny you talked about a variety of different groups who might be vaccinated - am I correct in thinking that what you are saying is that the SAGE did not say these people should be first, these people should be second, these people should be third, but that it put a strong priority on health-care workers but after that its somehow left in the hands of individual countries? And I would have a follow-up question.

**Dr Marie-Paule Kieny:** So you are right: the SAGE identified the health-care workers as a main priority group for the three reasons that I already have given. In terms of the other group it really depends on the strategy that each country wants to follow. In certain cases, as I mentioned countries may want to try to mitigate transmission and therefore, children would be an obvious target. In some other cases, they want to rather concentrate on reducing morbidity and mortality and then some other groups may be more the target. But there is identification on various options but no ranking and no priority are given to these options.

**Helen Branswell, Canadian Press:** The follow-up I wanted to ask in your presentation to that made in last week, you refer to the fact WHO has done a survey of vaccine manufacturers asking them about their plans and if I read the slides correctly, only 12 of the proposed pandemic vaccines are planned to have adjuvants in them. Is WHO getting a sense that a number of manufacturers are not planning of using adjuvants? And do you have a position on whether or not that is appropriate under the circumstances?

**Dr Marie-Paule Kieny:** Indeed it is very difficult in a situation like in a pandemic when you want to have a vaccine which can be distributed safely to the population in the shortest possible time, it is very difficult to say that you take the adjuvant of one company and you mix it with antigens of another company when they have never been tested together. So we know for example that clinical trials financed by the US Government have looked at some of these combinations but these are very specific combinations. So it is very difficult to imagine because as you have seen in the slides, manufacturers are actually, although the vast majority of vaccine doses is coming from companies in certain areas of the world, there are actually vaccines manufacturers in other parts of the world, and these are producing less vaccines in terms of output in number of doses, but it would be very difficult to say let us just for the sake of taking an example that you take vaccines from country X in Asia which has never been a mix of any of this new adjuvant and then you just make the mix and you say that this is my vaccine and it will be safe because the safety of adjuvant is not only depending on the adjuvant itself, it is quite often combined fact between the purity of the antigen of a certain characteristics of the antigen and the adjuvant. So this is why a number of manufacturers who currently have never made any other vaccines than non adjuvanted vaccines are still planning to go with non-adjuvanted vaccines. I may also add a comment on that for the time being there is still the question to know whether the immunogenicity of the A(H1N1) vaccine will be more like that we are used to for seasonal vaccine where no problem with 15 micrograms not adjuvanted, just one dose is fine or will it be more like H5N1 where all the trials have shown that you either need to have a very potent adjuvant or you need to increase the dose quite significantly, so in the absence of theses responses, yes a number of manufacturers are planning to go ahead with 50 microgram without adjuvant.

**Martin Enserink, Science Magazine**: Helen Branswell reported this morning or late last night from those presentations that the virus is not growing very well. I wonder if you can comment on that, and whether that will cause any delay? Secondly, has SAGE made any recommendations with regard to international solidarity? Is there any talk of any recommendations to create equity between countries, for instance you mentioned that countries can have different strategies but would it not be recommendable that they use only the vaccine for those high-risk groups and save vaccines for other countries?

**Dr Marie-Paule Kieny:** First, in terms of yields, maybe there is some confusion between the reality that is in the slides, that is now recognized by the manufacturers and the regulatory authorities and the WHO Network that we have a strain which are currently available to make inactivated vaccine, the manufacturers only get moderately affected yields. This is not to say that the viruses grow poorly, it is that for a reason or another the hemagglutinin they can produce is either not stable or very low. It is not known what is exactly happening but in terms of output that they have of hemagglutinin at the end when they grow a virus, they have poor yields, poor as between 25 and 50 percent of the normal yields that they have with good yielders. What is the reason for this is difficult to know, that it is well known that some strains are good yielders and some are bad yielders, it happens that for the first series of strains which were generated and unfortunately, we did not come up with a good yielder. So that in order to remedy to that the WHO laboratory network is again trying to generate new vaccines viruses from wild type virus isolated from patients, and these will be tested again by the manufacturers and we hope that at least one of them or more than that we hope will be giving higher yields that would be comparable to the ones obtained with seasonal vaccines. So for the time being, these are strains which are available and are still giving of course enough production yields in order to make clinical batches into test immunogenicity of new vaccines. We understand that the regulatory authorities have said that when better yielders are available there will not be a need to have bridging studies between the results obtained with the strains available now and the new strains because actually there will be difference in yields and not in antigenicity or immunogenicity. So we hope that as soon as possible the situation can be improved upon but for the time being there is no reason to be really anxious about that.

In terms of equity, yes of course, SAGE has also made a note that WHO should try to help with as much equity as is there in the distribution of vaccines. We are all committed to that, we have several strategies, we are discussing with the industry and we have already, this was announced in the press, we have already secured a number of donations from industry, we have also secured access to real time production during the pandemic. WHO at the highest level is discussing with Governments to see how much they can help to either help negotiate some doses with industry but also help finance these vaccines and finally, but very importantly, we are also discussing with new manufacturers who have started to acquire the technology to make influenza vaccines in the past three years with technical and financial support from us, to help them accelerate their preparation and be able to produce some vaccines for their own country. So this is the situation in terms of trying to ensure equity for vaccines.

**Richard Knox, National Public Radio:** Dr Kieny, you said earlier that you do not expect safety issues to arise with the pandemic vaccine and tests but do you think that there is less risk of Guillain-Barre syndrome with this new swine flu vaccine than there was in 1976 and why? And secondly, I wonder with the accelerated safety tests that will be necessary, how many subjects will you expect to have tested and how can experts draw conclusions about safety from these tests when the vaccine has put into a hundreds of millions of people.

**Dr Marie-Paule Kieny:** It is not completely known why the vaccine which was distributed against the swine flu in 1976 induced higher risk of Guillain-Barre syndrome. There are a number of hypotheses and one of the hypotheses is that the vaccine was contaminated by a component coming from a bacterial infection that was inducing antibodies that cross reacted with self protein and therefore, caused Guillain-Barre syndrome. The vaccines which are produced now are much better purified than the way they were in 1976, so we really do not think that it is likely that we will have these side effects again, but to be absolutely honest, of course it is only when you have a large scale distribution of vaccines that you know with certainty the safety profile of the vaccine. Modern vaccines such as those which are used to immunize children and adults currently in all countries of the world are very safe products. Nevertheless, in a very small numbers of people they do induce adverse reactions and this can be the case as well for adjuvanted vaccines and non adjuvanted vaccines. So what needs to be put in place and everyone is working towards this direction is a very good surveillance system and monitoring adverse effects so that as soon as a signal pops up it can immediately be followed-up, investigated and adequate public health measures be taken to respond to that. Now, in terms of these new vaccines, new adjuvants there is one manufacturer who has had an oil-in-water adjuvanted influenza vaccine in use for many years for seasonal vaccination and the safety database for this particular antigen is very large although mainly in elderly people and there does not seem to be any signal for any unexpected severe event like Guillain-Barre. But as I said, all must be put in place to detect any signal as early as possible.

**Journalist, Sky Television:** Your referred previously that the obese people should probably be among those that the national government should consider to vaccinate. On what scientific basis are made these recommendations and if you could elaborate more on the body mass index? And the second question is, if we have the vaccine later than October in the Northern Hemisphere, don't you think it would be too late to protect the people from the second pandemic wave?

**Dr Marie-Paule Kieny:** In terms of obesity, obesity has been observed as being one of the risk factors for more severe diseases other than H1N1 influenza. This is an observation. We still don't know exactly if it is obesity itself which is a risk factor, or if it is other health conditions which arise because of obesity. For the time being it is an observation and a lot of investigations are conducted to try and understand this better.

It has been observed in several countries that people with a body mass index over 30, and even more, over 40, have a higher chance of having a severe disease than noon obese people. This is why one of the groups that was mentioned, that was listed by SAGE, and that was worth considering for pandemic influenza vaccination contains all populations over 6 months of age with risk factors, and one of the risk factor listed is obesity. Its not the only one of course, you have asthma, chronic lung disease. All these are considered as being risk factors based on observation so far. About availability of vaccines, all the manufacturers and the regulatory authorities are working to have vaccine available as soon as possible. Vaccines will be available starting from September or October. If the situation remains as it is, of course the regulatory authorities will certainly want to have a better handle at the safety in clinical trials and dosing in clinical trials and these clinical trials will take some time, and therefore, to have a full license of this new vaccine may take until the end of the year. This being said, many countries have provision in their law, so if there is an emergency they can invoke an emergency situation to use vaccine for which you would have already good characterization in terms of pharmaceutical data but not yet, all the data on clinical trials. We certainly look towards seeing how the epidemic evolves and when it unfolds, to see what is the situation in countries and we will take our own decisions on whether or not to use vaccine under an emergency provision as compared to waiting for full registration of these vaccines.

**Maggie Fox, Reuters:** If WHO wants to reassess its best case scenario for how many vaccine doses might be available – I think the last number for the best case scenario was 4.9 billion. And I am also wondering about this issue with the virus strain not producing good results. Was this also the same for the live vaccine or only for the killed vaccine?

**Dr Marie-Paule Kieny:** In terms of updating the figures that we have published for likely vaccine supply over the next 12 months, we will update these figures but we want to wait to have some further information to update these with some meaningful changes. First as we have to have a definite idea of what yield manufacturers are getting with inactivated vaccines: is it the same as seasonal, which was the assumption that we took when we made the first calculation, or is it 50%, and these of course as you may imagine will change the total output. The other information which is still lacking as what is a dose of inactivated H1N1 vaccine. Is it, without adjuvant, is it 50micrograms, is it 30 micrograms, we don't know. And we will know as soon as the result of the first clinical trial will come out, although the result will certainly be very adapted or relevant only to the vaccine which will be tested, it will still give a flavour of what kind of results we will have with the other inactivated vaccines. You asked a question about the live-attenuated vaccine, the response and the way this vaccine induces an immune response is very different because these are replicative organisms, so they induce antibodies and also anti-cell response. So for the time being, the results that we have from the manufacturers who make live-attenuated vaccines, is that in terms of yields, and this is yields in terms of growth this time – how these vaccine strains grow – there does not seem to be any surprise and they grow with the same titres as the seasonal vaccine that they have obtained in normal production for a seasonal vaccine. Still there need to be clinical trials to know what titres of these live-attenuated vaccines will have to be used in a dose to make an effective dose. So the quick response is that we don't know, but in terms of growth they seem to be behaving normally.

**Journalist, Scrip Pharmaceutical News:** When the new pandemic vaccine becomes available later this year, will WHO or Member States have any new pharmaco-vigilance initiative to pick up ADRs to this new vaccine. For example, in some countries, they allow patients to report ADRs as other do not. Is WHO thinking about this or are you quite happy with existing pharmaco-vigilance systems?

**Dr Marie-Paule Kieny:** Although in some countries the pharmaco-vigilance system is working very well and we will pick up signals very easily, in other countries there need to be an increased attention to the pharmaco-vigilance system, notably in the developing countries and WHO is already working with countries to try and use systems in place, like the system that the Polio Initiative uses to detect cases of acute flaccid paralysis to try and help detect any signs of Guillain-Barre for example. We are both strengthening the network as well as working on new guidelines that will be more adapted to the detection of adverse events following vaccination with pandemic influenza vaccine.

**Helen Branswell, Canadian Press:** I would like to get some information about adjuvants and children. Obviously young people are among the people hardest hit by this strain so far but I don't think that there is much evidence at all about safety of adjuvants in that group. I was looking at a document yesterday that shows that with MS59 for instance, it has been given to 6 or 700 children which is not a long safety record. Are there any other vaccines – not influenza vaccines – but marketed vaccines with these kind of adjuvants that children receive now and that might give us a sense of whether or not they are safe to use in children?

**Dr Marie-Paule Kieny:** You are absolutely right that safety data, at least in terms of numbers are lacking in certain population groups. You mentioned the children, certainly there are no data in children more than 6 months old and less than 3 years, there are no data in pregnant women, there are no data in asthmatics, so there are quite a number of populations for which there are no data. SAGE has also made the point that as quickly as possible data should be obtained on these populations groups if they are to be vaccinated with these new vaccines. In terms of use of this new novel adjuvant in children, there is no vaccine for very young children that is using the formulation. The closest being the vaccine which is currently developed as the malaria vaccine, which has been tested in a few thousand children and is being tested now in Africa with this indication for malaria in a few thousand children, but apart from that, these data are still lacking.

**Journalist, German Television:** If I understand correctly, talking about the doses for the next winter, do we have to go for a mid-seasonal vaccine and then also to go for two other doses for the new pandemic vaccination, will there be enough vaccine for all the countries then?

**Dr Marie-Paule Kieny:** The vaccine against seasonal influenza for the Northern Hemisphere is finishing production. We expect to have more than 90% of doses which were planned to be produced, so this is very close to the number of doses that were produced in 2008. We don't envisage changes in the recommendation for seasonal vaccination, so vaccination will still target the same persons and as in the previous national recommendations mainly in most countries these people will be the elderly, over 60 or 65 years of age, also in some countries children as well, so yes, certain of these groups may receive during the upcoming fall three shots which could be one of seasonal vaccine and two for the pandemic vaccine.

**Mr Gregory Hartl:** Dr Kieny, thank you very much. That closes our virtual press conference for today, 13 July, from WHO headquarters in Geneva. And just before we say goodbye, one last reminder that there will be 3 things posted on the WHO website shortly: the normal audio file and transcript and in addition, a web update which outlines recommendations from the SAGE meeting will also be shortly available. Goodbye.

# Transcript of WHO Virtual Press Conference of 6 August 2009 with Dr Marie-Paule Kieny, Director of the Initiative for Vaccine Research at WHO Headquarters and Gregory Hartl, Spokesperson for H1N1

**HARTL**: Good afternoon. This is the World Health Organization in Geneva. Welcome to our virtual press briefing for today 6 August 2009.

With us today is Dr Marie-Paule Kieny, Director of the Initiative for Vaccine Research here at WHO headquarters who will brief you on developments regarding vaccine development for pandemic H1N1 virus. So just to let you know that after the VPC is over we will post as soon as possible thereafter an audio file and a transcript. For those of you who would like to ask questions, please dial 0 1 to enter the queue.

Thank you very much and welcome and I hand over to Dr. Marie-Paul Kieny.

**KIENY**: Thank you very much. So in my update on vaccines, I will cover three points.

One is the state of development of the vaccines. Second, I will try to address concerns that have come into the press about safety, and finally I will also talk about future availability and how we see at this point as of today when this vaccine will be available first for use.

So about status of development first. As you know the vaccine viruses, which are really the starting material that the manufacturers need to produce vaccine, have been provided to all manufacturers. There have been more than 400 shipments of viruses and reagents to the manufacturers. So all this has been now mastered by quite a number of weeks by the WHO Collaborative Centres.

In terms of real production, the manufacturers have adapted these vaccine viruses to grow in their particular conditions, and they have produced lots of batches if you wish. So these are the material, it’s concentrated, it's an experimental vaccine that can be now used for clinical trials and some of the batches, the larger batches, are also the ones that will be used for real application and implementation of vaccination campaigns.

So the data and all the controls on these vaccine lots are being submitted right now to regulatory agencies, in order to allow these regulatory agencies to look at the data presented by the manufacturers, and to take decision on their safety and suitability for use in the population.

In terms of clinical trials, we have now seven manufacturers who have started clinical trials and these clinical trials as I speak are going on in at least five countries. These countries are China, Australia, the United Kingdom, Germany and the U.S.A. We expect that more clinical trials will start in the days to come, really this is something which is happening as we speak today and these clinical trials will of course be conducted in additional countries to the list that I just gave.

So when do we expect to have results of the first clinical trials and what will the clinical trial results tell us?

So for the clinical trials that have started in July already, we should have early results during the first half of September.

What will these trials tell us?

They will tell us whether we will need one or two doses per person for vaccination. You certainly know that for seasonal vaccination it is only one dose that is required. For H5 Avian virus, however, there was a need to have two doses of vaccine per person to induce the level of protection that would be required against an infection. So we will know after these clinical trials whether one or two doses are needed and this will also give confirmation that the formulation that the manufacturers are using are indeed immunogenic and are likely to induce protection again the pandemic virus.

So really in conclusion in terms of development we are on track in development. We have put on our website in Vaccine Question and Answers, that it takes between five and six months to develop a new influenza vaccine for a pandemic application. As you will calculate we are absolutely on track with that and WHO will post as of today a new document on our website which will really detail the different steps which are needed to make a pandemic influenza vaccine, and details also on the length of the steps and description of how it takes five to six months.

The next point that I would like to cover is on safety.

So there have been concerns voiced in the press but mainly the time lines for the development of these vaccines is so quick that it would not assure safety. So I would like to make clear that for all vaccines have a safety profile. There is no vaccine that induces zero safety concerns. Most of the safety concerns induced by the vaccine which are apart from that, very, very safe medicines, as (unintelligible) some fever sometimes, potentially nausea, so very minor side effects, but in a very rare occurrence from many vaccines, there can be the occurrence of a more severe adverse event. So there is no doubt that if and when there will be very large scale vaccination campaign, there will be people who will have an adverse event. The large majority of these events will not be associated at all with the vaccine which is given. It will be temporally associated which means this is something that would have happened anyway, but which just by chance is happening after a person has had a vaccination.

So the regulatory authorities in all countries will monitor very closely all sickness as adverse events, and will try immediately to decipher whether indeed these side effects are linked to the vaccine, or whether they are just coincidental.

In terms of assuring most specifically the safety of influenza vaccines, I would like also to point out that part of the vaccines are based on very old and proven technology which are used for seasonal vaccination.

So for seasonal vaccines, million upon millions of doses have been administered to all kinds of populations, including very young children, and including pregnant women. For those vaccines where the technology remains exactly the same as for seasonal vaccines, what happens or the way it is treated, is called a "strain change". So this is no different to making a vaccine for the seasonal flu in 2006 and making the change to making the 2007 vaccine. So regulatory agencies in the world have different ways of treating these so-called strain changes.

In the USA for example, the FDA approves a strain change by looking at the quality control dossier that the manufacturer submits and does not require a clinical trial. Therefore, for those pandemic vaccines that will be like a strain change, only it will be H1N1 instead of another seasonal strain, the FDA has decided that they will treat this as a normal strain change and, therefore, the vaccine will be registered without clinical trials.

All manufacturers of course will conduct a clinical trial if only to confirm whether one or two doses are needed as I said a few minutes ago.

In Europe the procedure for registration of seasonal influenza vaccine is slightly different. In the sense that the regulatory authority requests every year a small clinical trial of the new seasonal vaccine. Therefore, in Europe, for those vaccines that are made using the exact same procedure, they are copies if you wish of seasonal vaccines, the European regulatory agency will review the dossier, will request a small clinical trial, and will register after that exactly like for seasonal vaccines.

Now for pandemic use, there are a number of vaccines which are not the classical seasonal vaccines. These are the vaccines which have an addition of an adjuvant. These adjuvanted vaccines have been tested extensively at the time when all manufacturers were preparing vaccines for a potential H5N1 pandemic. In view of the potential gravity of an H5N1 vaccine, the European Regulatory Agency had designed a special process by which manufacturers would test extensively in clinical trials, prototypes of H5N1 vaccines, including with adjuvants, which submit all the safety data of clinical trials, immunogenicity to the regulatory agency and obtain what is called a "mock-up registration". So this is a registration for a prototype.

So those manufacturers who do have a mock-up dossier can go and present to the EMEA all their documentation for the H1N1 vaccine and as previously agreed already in 2007 with the regulatory authority, obtain registration without clinical trials. But again as I said for the USA, all manufacturers will conduct clinical trials and the earliest results of these clinical trials will be available in September.

Finally, about future availability. Well, as you know, it is one thing to have vaccine lots, even commercial lots ready in the fridge, and to be able to use it in the population. So the step which is required in between having the physical material ready, and using it in the population, is "licensing" by regulatory authorities. Now the manufacturers have started now to submit these dossiers to the regulators and to expect that the regulators will make decisions on these vaccines that will allow use in populations during September when the first authorization may be in September, and then going further into October, when the dossiers are ready and are submitted by the manufacturers.

So with this update I will be very happy to answer any questions that you might have.

**HARTL**: Dr Kieny, thank you very much for that very thorough update. Now before we go to questions can I please remind journalists that there will be an audio file available almost immediately after this briefing is over, and shortly later, there will be a transcript on the web site. For journalists who are wanting to ask a question, please dial zero one (01) to get into the queue.

The first question is from Jonathan Lynn of Reuters.

**LYNN**: Could you tell us something about the likely yields of the vaccines that are being developed at the moment on the basis of the trials.

**KIENY**: The early yields that the manufacturers have obtained with the vaccine viruses, with the seed that they have made out of vaccine viruses that have been provided by WHO Collaborative Centres, have been quite disappointing. Indeed we have had news and discussions with all of the manufacturers and they were reporting yields which were between a third and a half of what they usually get for a good seasonal strain.

So this is certainly of concern because this would mathematically result in a reduction by the same factor of a production capacity. So the WHO Collaborating Centres have been starting immediately to produce new vaccine viruses and we need to wait for a few days to have real confirmation but the latest result that we've heard as of this week is that at least one of the strains which has been produced, seems to have been promising and seems to give equivalent or similar yields as the ones that the manufacturers have for seasonal vaccine. So I don't want to say too early that the question (situation) has been resolved but it really seems we have found a way to go around this problem.

**Mr GOLD, DPA**: Hi, thank you very much for taking my question. I just wanted to ask one thing, when you mentioned the names of the countries that are doing research you didn't mention Switzerland. But Novartis announced that they have begun clinical trials.

Is that from the US arm, or is it not something WHO has been told about? And what is the possibility there are a lot more trials going on that maybe the WHO is not aware about?

Secondly, because the sound was rather bad, could I ask you to just repeat very briefly the European regulations and how the Europeans are going to be testing the new vaccines.

**KIENY**: So as to countries, Novartis to the best of our knowledge, has started the first trial in the UK and this was a vaccine they had produced using "cell culture" and not in eggs and since then they have also started clinical trials in Germany and in the US. So of course, as clinical trials start these days, right now, it may well be possible that another clinical trial is starting today that we don't know about. We do have communication and an excellent relationship with the regulators and the manufacturers and we have really frequent update of the latest development. So yes it may well be that another clinical trial has started somewhere else.

So going back to the registration of influenza vaccines in Europe.

What I said is that the normal registration procedure in Europe for seasonal vaccine includes a small clinical trial. And this is for a seasonal strain, which is therefore, a change from one year to another is considered as a "strain change." And in Europe, in addition to reviewing the dossier that the industry produces, the European Medicines Agency also request the results of a small clinical trial.

So for vaccines which are the same as seasonal vaccines, if you wish, using the same procedure, just in changing the strain, the European Medicine Agency will of course continue to request a clinical trial.

For those vaccines where the formulation that is proposed by the industry is different from that of the seasonal vaccines, which is based on the formulation, which has been discovered if you wish, or developed, for H5N1 pending future or potential future pandemic vaccines, for those manufacturers who have what is called a "mock-up registration" so this is a registration of a prototype pandemic vaccines, the agreement and the procedure that was reached already in 2007 was that in order to ensure as early as possible the availability of vaccines, that the manufacturers could submit their quality dossiers, so this is all the results on characterization of a protein, and also of course toxicity, all lots of vaccines are tested in animals for toxicity, so that if preclinical studies on all vaccines, and could submit this dossier and that they could be approved without clinical trials. This is a procedure which is nothing new and has not been invented for H1N1. This is something that has been put into place at a time when we were more worried by H5N1 than by the current pandemic.

**MICHELE CORTES, BLOOMBERG:** Yes, I'm wondering if you can tell us how many doses we are going to expect of the adjuvanted vaccine and the regular seasonal strain, where you have the strain changed. And also in the US where they don't have any adjuvanted vaccine at all at this point, I'm wondering what the process will be there in terms of either using the strain change or adjuvanted vaccine.

**KIENY**: So let me address the second question first. The US regulators will approve vaccines which are based on the seasonal production process, as I said. For the others of course they will look at the adjuvanted vaccines but because these vaccines have never been licensed in the US there is not an adjuvanted flu vaccine registered in the US nor any vaccine, as a matter of fact, against any infectious disease based on this new adjuvant; contrary to what is the case in Europe the US regulators will request to review ..result of … development, like for any new vaccine because for them this vaccine will be completely new.
Now in terms of the capacity, again I would really like to avoid making any projections right now. When H1N1 started we said if the yields are as for seasonal, if full capacity is used and if each manufacturer can use its most dose-sparing formula for the vaccine, we may have as much as 94 million doses per week. This was a best case scenario and before we make any other projection we would really need to see what are the real yields because as I said, a few weeks ago we were seeing results indicating that the yields would be at best, only half and therefore you would have to divide total capacity by factor two. Now we are hearing that it is getting better so instead of changing prospects every day or every week, we prefer to stay on this best case scenario and to give a much better and really firm response when the yields are known and also when there is a confirmation of the efficacy of the vaccine which are tested right now.

**HARTL:** Thank you very much. The next question is from Martin Enserink of Science Magazine.

**ENSERINK:** Thank you for taking my question. I actually have two that are related. First of all I wonder do you prefer, as much as possible, adjuvanted vaccines to be produced and used and if so, what ways do you have to encourage countries and vaccine manufacturers to do that. Secondly, you have said in the past that ensuring supply for developing countries is one of the top priorities for WHO. Where do you stand on that because there have been very hard facts announced about that?

**KIENY**: In terms of adjuvants, of course as WHO has already said and stated, we have reviewed the safety of adjuvanted vaccines as they have been tested for H5 and also, as they are used and now more than 40 million doses of adjuvanted flu vaccines have been used in Europe already, so we see no apparent safety signal and really think that the Organization, based on expert advice - this is not the Secretariat opinion, this is based on expert advice - that there is no safety concern with using adjuvanted vaccines. As I said, of course, there will be side effects. People will have sore arms and may have dizziness and there may be more rare severe side effects but there is no signal to that for the time being. So, manufacturers will use adjuvanted vaccines, there is no doubt they are producing those and they will be used in quite a number of countries and even the large users of vaccines will be testing and consider using adjuvanted vaccines when they have been tested in clinical trials.

Now in terms of availability for developing countries, as you say, WHO is really trying to ensure that all countries, including developing countries, will have access to vaccines. So, the recommendation that we had from our highest advisory body on immunization on 7 July, the Committee is called SAGE - Strategic Advisory Group of Experts - WHO has made the recommendation following the SAGE meeting that all countries should immunize, at the minimum, their health workers. We are in line with this and are discussing with manufacturers about having access to their production capacity, either through donation or through access real-time to their capacity at a reduced price, at a more affordable price on behalf of developing countries and we are really striving to make sure that the quantity of vaccine that WHO will be able to access directly, not talking about what the countries negotiate themselves, will cover at least these populations.

In terms of donations, we have had two generous donations as you know - one for 100 million doses and the other for 50 million doses. We are discussing with other manufacturers but all the manufacturers are really looking forward to having better knowledge of the yields and therefore of what the real capacity will be before committing to a donation but we are confident that the vaccine that we will be able to acquire as I said, a vaccine to distribute to all countries, not to cover the whole population of course.

**HARTL:** Thank you. The next question is from Mr Gailano from Dow Jones.

**GAILANO**: I was wondering if you could give us a bit more details of what kind of side effects we are looking at, if they were to occur and also if you could maybe elaborate on the probable time that will elapse between the first results and the actual deliveries of the vaccine, presumably towards the end of the year. Thank you.

**KIENY:** In terms of side effects, what will be monitored are the usual side effects of the vaccines which, as I said are fever, pain, nausea, diarrhoea, fainting. In addition what we will really look with great scrutiny by all involved in post-marketing surveillance will be what is called Guillain-Barré Syndrome, which is a very rare side effect which happens sometimes after vaccination. It is not something which has been described for seasonal influenza vaccination. It has been described in one situation which was in the 1976 vaccination against Swine flu in the USA but even there it was a very rare event - 30 people died out of 40 million people immunized. This is always a tragedy there is no doubt but we are discussing 30 people as compared to 40 million vaccinated. Because of this event, the causes of which only are only starting to be understood and not completely, all the post marketing surveillance will certainly be very wary of this possibility of this Guillain-Barré Syndrome and will follow this very closely and a procedure put in place in countries to be sure that even in low income countries it will be possible to detect this side effect very early. Now, in terms of availability for use, as I said it will depend on the regulatory decision if regulators license, as we think it is likely, the vaccine in September it may be the case that some countries may already start vaccinating in September.

**HARTL:** Thank you very much. The next question is from Signor Ezzekial Ignoguran from La Razon in Argentina. Go ahead please.

**IGNOGURAN**: Thank you. I want to ask if there will be any kind of support programme for developing countries to get the vaccine.

**KIENY**: In terms of support for procurement of vaccines, yes, as I tried to explain, WHO is negotiating with the manufacturers to have access to vaccines for developing countries and this is through donations or purchase at a reduced price so we will assure a minimum level of coverage in all low-income countries. In terms of countries in the Latin-American region, as you know, there is a mechanism which is in place called the PAHO Revolving Fund by which the Pan-American Health Organization procures, buys vaccines on behalf of Latin-American countries. Our colleagues at the Pan-American Health Organization are already also discussing with manufacturers the purchase of vaccines for the Latin-American countries in terms of covering the population with H1N1 vaccines so I would really encourage the Latin-American countries who are not yet in contact with PAHO to contact this organization.

**HARTL**: Thank you, the next question is from Deutschland Funk, go ahead please.

**DEUTSCHLAND FUNK:** I would like to know how similar the vaccines which are now under development are to the vaccine from the 1976 vaccine in the US which caused Guillain-Barré Syndrome problems.

**KIENY**: The vaccines are very different. Of course they are also similar in the sense that both are made out of influenza virus grown in eggs so this is the similarity. They are very different in the sense that the degree of purity that is obtained now with the vaccine which is used now both for seasonal and with the use of pandemic vaccination was much less advanced in 1976 so there were very many more impurities in the vaccines. I must say also that for people who sometimes who are worried about association of adjuvants with Guillain-Barré that at time in 1976 the swine flu vaccine which was associated with the Syndrome was not adjuvanted so, yes, they are similar in the sense that they are all influenza vaccines but their formulation, what they are made of, and the impurities which are present in today's vaccine, the modern vaccine, is much less than what we had 30 years ago. So the vaccine that we have now is much purer and the quality controls and testing in the laboratories which is made on today's vaccine is much better than that of 30 years ago.

**HARTL:** The next question is from Helen Branswell from Canadian Press.

**BRANSWELL:** Dr Kieny, you were talking about the fact that there could be some temporal associations drawn between the vaccine and things that happen to people after they get it. Right now vaccines are undergoing a lot of scrutiny, there is a lot of scepticism about them in some very affluent societies, such as the US and the UK. Are you concerned that this mass vaccination campaign could actually create problems for the reputation of vaccines?

**KIENY**: We hope not because vaccines are really one of prevention methods against infectious diseases which is the best in terms of efficacy, the safest and really we are always worried when there are rumours of vaccine safety and most times, these rumours are unfounded so it needs to be reacted to very quickly. This is why we hope that by the time that the vaccine will be implemented we will have everything in place at least in the first country which vaccinates to make sure that sickness can be picked up very early and also that any cause of an adverse event, apart from vaccine, can be found as quickly as possible so that these cases of side effects, which will occur as I said, can be explained. I think we will have to work very quickly in detecting them, explaining about them and communicating to the press and we hope that we will have the assistance of the press to help us dissipate, when it is appropriate, as soon as possible these rumours about vaccines being unsafe.

**HARTL:** Before we go to the next question, can I thank journalists for having come on line today and let you know that we unfortunately only have time for a few more questions. The next questions is from Bob Rose of Telegraph News Service.

**ROSE**: I was wondering if in some countries, such as the US, if people may be getting seasonal flu shots and the H1N1 vaccine at the same time or possibly in quick succession and if there is any concern about the reaction to the seasonal vaccine, dampening the immune response to the H1N1 vaccine ….. antigenics and I wonder if there is much concern about that.

**KIENY**: I don't think that there is concern for the time being so the population that for receiving seasonal vaccines and the first time of receiving H1N1 vaccine are not completely overlapping - they are in a sense but not completely so it is not at all a fact that a person will receive the two vaccines on the same day and then we will have to follow up to see what is the immune response but for the time being there is no cause for worry especially for vaccines because the influenza vaccines are really vaccines which are very well known in terms of the seasonal use of these.

**HARTL:** The next question is from Mr Schmidt of Der Spiegel.

**SCHMIDT:** There have been specific concerns raised about the adverse events in pregnant women especially because there has not been a lot of testing of vaccines on pregnant women obviously. Are there any plans to use non-adjuvant vaccines in this kind of group?

**KIENY:** As you rightly point out there is no experience with using adjuvanted vaccines on pregnant women - there is a lot of experience of using a seasonal non-adjuvanted vaccine so to answer your question I would like to refer to the recommendation of SAGE on 7 July where it says that in view of the fact that pregnant women seem to be a group at risk of more severe adverse events and potentially of death with the H1N1 pandemic, the recommendation of SAGE was that pregnant women should be considered as one of the priority targets for vaccination and SAGE goes further in saying that in countries where un-adjuvanted vaccines are available these used be a priority use for pregnant women but that in countries where there is no availability of un-adjuvanted vaccines then governments should consider using what is available in the countries, which means either live attenuated or inactivated adjuvanted vaccines in view of this benefit.

**HARTL:** Next is Mr Uoro of CTV Canada.

**UORO:** I have a question about whether the vaccine's safety will be profiled in those who have already had the disease. There are a lot of patients who come down with this disease but do not actually have the symptoms based on the data from Peru. This sort of follows into another question which is, what is the progress in the development of serology, that is to say blood tests, in determining past exposure and also better determining case fatality rates of this disease based on many who may have been exposed and not realised it.

**KINEY:** In terms of testing the vaccine first in those who have already been infected by the virus I think there is no plan to do that so the vaccine is being tested in normal healthy volunteers without exposure to the H1N1 virus so far and I do not know of any plans to test it in previously exposed persons. Development of the diagnostic test is of course on-going. I do not know either of any plan for testing people before giving them the vaccine and actually, such a test would be very costly, delay vaccination campaigns and there is no reason, based on safety, why this should be done at this stage. There was another question.

**UORO:** Do you foresee a safety concern in giving someone the vaccine if they have already had the disease and should there not be careful monitoring to make sure that giving the vaccine to someone who has already had the disease does not have an untoward or increased risk of side effects?

**KIENY:** There is absolutely no reason to think that somebody who has had the disease already have any adverse event following immunization and this is based also on experience with other vaccines including influenza vaccines. So these adverse events will be monitored very very closely and yet it appears that the detection of somebody who had the disease and then had the adverse event, will be investigated very closely but for the time being there is no concern regarding this point based on previous experience with other influenza vaccines of course.

**HARTL:** The last question today is from Agence France Press here in Geneva.

**AFP:** Greece announced that they are planning to vaccinate the whole population. Do you think this is realistic and do you suggest to governments that they should do the same since there is not enough vaccine.

**KIENY**: What SAGE has said is that they have given a recommendation to vaccinate at least the health workers and then has listed a number of groups which are potential targets for vaccination according to the strategy of the country and this is really a government priority to see what they want to achieve with vaccines or with using an antiviral or with use of other prevention or treatment methods. Some countries have decided to vaccinate their whole population - there is no indication that this would be unsafe so it is again a strategy of a country to protect its population against influenza pandemic. Not all countries which could have access to enough vaccine have chosen to do this, again it is a choice of strategy which is the country's choice.

**HARTL:** Thank you very much again Dr Kieny. This has been the virtual press conference from WHO Geneva Headquarters for 6 August 2009 and thank you to all the journalists online for having participated. A final reminder - the audio file will be available shortly on the website and a transcript will be available later. Updates are always available on www.who.int. Thank you.

# Transcript of virtual press conference with Gregory Hartl, Spokesperson for H1N1, and Dr Marie-Paule Kieny, WHO Director of the Initiative for Vaccine Research, World Health Organization

## 24 September 2009

**Gregory Hartl:** Welcome to the WHO's virtual press briefings, today Thursday 24 September 17:00 o'clock Geneva time. My name is Gregory Hartl. The speaker today is Dr Marie-Paule Kieny, who is the Director of the Initiative for Vaccine Research, at WHO Headquarters, and she will in just a second or two she update you about what is happening with H1N1 Pandemic vaccine. One or two house-keeping matters before we go to Dr Kieny, to let you know that tomorrow, Friday, on the WHO website, you can expect to see the weekly update on the epidemiology of the pandemic and secondly, there will be an update tomorrow on antiviral and antiviral resistance. Today is for pandemic vaccine and the transcript will be up tonight on the WHO website. Welcome. I will turn over now to Dr Kieny.

**Dr Marie-Paule Kieny:** Thank you Gregory. Good morning and good afternoon. It is a pleasure to have this opportunity, to give you the briefing on pandemic vaccines. I will try to address 3 points successively, and will try to discuss when the vaccine will be available, the second point is how much of it will it be, and the last point is for whom.

So in terms of when, vaccine development is on track. In May, we announced that it will take about five months from the time of the identification of the pandemic virus to the time the first vaccine will become available for use, and not for experimental trials. So here we are and the first vaccines have indeed been licensed and plenty of results have come out of clinical trials, in China, in the USA, as well as some other places in the world. These trials have actually given very good news, and have demonstrated to immunize a protective level of immunity with a single dose of vaccine, at least in the general population. Special populations, eventually children, people with immuno-deficiencies may need to have more than one dose, but in the vast majority of people, one dose will be sufficient.

The big impact of this is that with the same dose of vaccine, we will be able to immunize as many as twice the population. The second good news is that, a formulation which has been shown to work with the normal seasonal vaccination, seemed to work very well with this pandemic virus. So is this surprising? Yes, and no. Some people predicted that may be it will be possible, but many people thought of as an example of the effort they had to develop H5N1 potentially pandemic vaccines, and for H5N1, it had been very difficult to make vaccines, in the senses that either you need to have very high doses or to add adjuvant in order to reduce the dose, or/and of course, to use two doses. So this is very good news, and it shows that all manufacturers who are producing usually seasonal vaccines, will be also to make pandemic vaccines and that there will be no problem of access or intellectual property rights associated with/to adjuvant, of which most of them are proprietary.

So vaccines have been licensed in a few countries. The first country to license is China, and China has also been the first country to have reported the first clinical results. This has been followed by other countries. The US FDA has licensed vaccines as well as Hungary and many countries will come now and follow suite.

Why is then that not all countries have licensed vaccines? Well not all vaccines are equal. Vaccines which have been licensed right now are vaccines which are similar to traditional seasonal vaccines, and in these, they are not new vaccines, and are registered by the USFDA, for example, a strain variation variation of seasonal vaccines. For some newer vaccines in a number of countries, they will need to have a bit more time to look at the dossier with more scrutiny, I may say, because this will be considered as new and therefore certain vaccines may take a little bit longer to be licensed and this due to the consideration. The overarching consideration that national regulatory authorities are given to safety.

Now these vaccines are here, today. They will not be all. All the doses will not be available on the first day. This is quite obvious. They had started now to be deployed. The first country to deploy was China, and the Chinese have reported that 34,000 people have been immunized in the area of Beijing. Other countries are following suit. Hungary has indicated their intentions to start a roll-out vaccination campaign, on the 29th of September, so this is next week, and other countries will follow suit.

Safety? Well, there has been a report of 14 of these adverse events in China. Out of 44,000 vaccinated all these adverse events have been reported were mild. Many of them may not even be associated with the vaccine. And this is about the range that you will expect for any seasonal vaccine or any vaccine as a matter of fact. There is dizziness, headache, something which is quite common, when we administer vaccines.

So is there a chance that there will be more adverse events, yes of course. There could be and these volunteers will need to be followed a lit bit longer than what we know from the outcome of the vaccination right now. And it may be when millions of population are vaccinated, there would be some incidents of severe adverse events. So these adverse events will either be investigated, all of them, and then the investigators will find that either yes, they are associated with the vaccines, and immediately, this will prompt more research into seeing if other people receiving the same type of vaccines also have had adverse events. But the vast majority will be unrelated. Because when you vaccinate thousands and millions of people, of course, some of them were going to have heart attacks, some women were going to have miscarriages, and these may - because they have just been vaccinated – be associated in the mind of people with vaccinations. So there will need to be some careful analysis, to try to see which adverse event, which is really a worry, is associated with vaccination, and which are only co-incidental.

Now, we have tried to address the when, so how much? At the beginning of the pandemic in May, WHO had conducted a survey, with all manufacturers that we thought will be able to make potential pandemic vaccine and we asked 36 manufacturers to give us what will be the prospect for capacity to make H1N1 vaccines. We had a 100% response and 26 manufacturers indicated their willingness to make pandemic vaccines. We asked them also to indicate how much they would be able to produce, which gave us a total of a little bit less than a 100 million doses at the best, in the best case scenario per week, which, saying that a year had 52 weeks, by just calculating and extrapolation of the weeks per production capacity to a year, gave us a total production capacity of a little bit less than 5 billion per 12 months, 4.9 to be more precise, but of course, this was a theoretical number.

Where are we now? And are the assumptions that were underlying figures still thought as being realistic?

Not all of them.

The first assumption was that, the yields for the quantity of vaccines that the manufacturers could produce would be similar to what they routinely have seasonal vaccines. You have seen that we have discussed numerous times that the yields were not good. We are talking recently about a third to a half of what they would expect. Now there has been good news and we know that the yields that are obtained with the latest strain which have been given to the manufacturers, are closer to what they obtained usually with seasonal vaccines, but not completely quite there yet. So the yields are a little bit lower.

The second assumption is that they will be able to produce, the formulation which could give the most dose-sparing effect that they had and this is still the type of assumption that we think is correct right now. And the third assumption was that they will be producing only pandemic vaccines in their facility where they can make flu vaccines. So this we knew was unrealistic because as you know there is need to have seasonal influenza vaccines for the southern and northern hemisphere, and because of downtime that the manufacturers will have to implement in their production plan, we know that this figure of 5 billion doses, per 12 months, will not be reached. How do we think that the figure will be, right now? So our latest assumption is 3 billion doses per 12 months, into the pandemic, and we will launch another survey with the manufacturers in October, to try to refine this prediction, and to base the new figures that we will able to give on actual data and responses directly from the manufactures.

Third point, for whom. Who will get the vaccine? Well, of course the first countries to receive the vaccines will be two categories of countries. First are the rich countries, with a high income. These are the ones which have already in the beginning even before the pandemic started, purchase agreements with manufacturers. They will be served first, because they have binding contracts with the manufacturers and some of them have already received vaccines in their countries and are ready to start vaccination campaigns. The other type of countries to be served very early with the vaccines is the countries that they do not have to be rich, but who have domestic production. Among those is China, as being demonstrated by the fact that China has already started to vaccinate. Another country, maybe another producing country although we do not have the precise data, may be Russia, or others. So other countries will follow suite and we will see in which order they start to vaccinate.

Which population should be the first ones to be vaccinated? The WHO SAGE, which is the Strategic Advisory Group of Experts, the highest level of advisors to the Director-General on immunization matters, has recommended that all countries should vaccinate their health workers. These would represent about 2 percent of the world's population, and WHO is working currently with donors, with manufacturers, through donations, and when we have, or when we do not have enough donations, we have a purchase agreement with the manufacturers to obtain vaccines at reduced prices for the developing countries. We are trying, the Director-General has announced that she will try to obtain enough vaccines to be able to provide to countries in need, which are the countries that will not have access without WHO, to cover up to 10% of their population. So this will cover - about 2% of the population that will be health workers, and other populations to be decided among the priority groups by the national governments. Indeed the choice of a population to be vaccinated is a national prerogative and each country will have to take this decision in view of their own epidemiological and national characteristics.

So we hope that the vaccines will be made available to most people in need, in all countries as quickly as possible. WHO expects to receive the first doses of vaccines to be distributed to the poor countries somewhere by end of October; we may be able to start the first delivery during November, or this is still exactly to be defined. We need to discuss with the governments of the receiving countries to see when they will be ready to receive the vaccines.

Now there have been many questions about the health workers. Does it mean that the fact that WHO has recommended that health workers should be vaccinated. Does it mean that there will be an obligation for all health workers to be vaccinated? Well, WHO does not recommend that vaccinating is mandatory. It is up to a person to decide. It is a voluntary choice to be vaccinated. Nevertheless, there are plenty of reasons for health workers to be willing to be vaccinated. One is to protect themselves because they may be more exposed than other people because they will be caring for sick patients, with the H1N1 pandemic flu. The second is also to help maintain a functional health system, because if health workers are sick and have to stay at home, then there is nobody to take care of the patients from influenza or other patients. And the third reason, which calls really upon the social responsibility of the health workers, is that health workers who would be sick with pandemic flu, are or will be putting their patients at risk of getting infected themselves. So for all these reasons, we think that they are good reasons for the health workers to seek vaccinations against pandemic flu.

So where are we now with WHO in terms of working on access for pandemic influenza vaccine? As we have said before numerous times, we have been offered 150 million doses from two manufacturers. This is still the same. We are discussing with more manufacturers who have expressed interest to give us vaccines. There has been also announced very recently in the press and we are discussing with governments that some nine governments right now have made an official offer to WHO to give up to 10% of the supplies that they have bought for themselves. And we really look forward to discussing with those and other governments and other stakeholders, to help to get more equity in the distribution of this very important vaccine. Indeed as you know again, vaccines are the most important tool to combat infections and pandemic influenza vaccine, and pandemic influenza in particular. So we count on the generosity of the governments of the manufacturers to help WHO and the international stakeholders to make more equity in this world. Thanks for your attention.

**Gregory Hartl**: Dr Kieny, thank you very much. Now before we open it up for questions, just a couple of reminders, that the transcripts and the audio file for this briefing will be available on the WHO website, shortly after the briefing is over, and to all journalists listening if you would like to ask a question, dial 01 on your keypad to enter the question cue. So the first question is from:

**Frank Jordan, Associated Press:** Hi Dr Kieny. It seems obvious now that not all of the world's population will be getting the vaccine in the first year. In fact, you said there will only be 3 billion doses available. So the question is how are you going to prioritize and what percentage of the population definitely needs the vaccine? I will appreciate if you could talk a little bit about that, and also mention which populations you think will need two doses.

**Dr Marie-Paule Kieny:** In terms of the countries, we think that, as already said, all countries will need access to vaccines so we are working with the Regional Offices to identify those countries which are the most in need. Our estimate is that we will have to cover countries accounting for about three billion of the population so a little bit less than half of the world and as I said we intend to provide these countries up to 10% of the population-worth of vaccines and will use the 150 million doses/donations that we have from manufacturers as well as donations from governments and we will also purchase vaccines if needed. So who would be in this population? As we said, the health workers would be the first priority and then it would be up to the decision of the national governments, they would consider, of course, people with underlying health conditions such as people with asthma, with a cardiac condition, people with immunodeficiency, people with other health problems of all ages, pregnant women and other minorities for some countries - so it will really be each country's government to make a detailed analysis of which population at the national level will most benefit from pandemic immunization.

So of course we are lucky that the pandemic is moderate in severity that most people experience a mild illness and recover spontaneously, therefore although one would want to protect everybody. Of course one always wants to give the maximum protection to everybody, it is also clear that most people will do well without vaccines. In terms of the number of doses it is clear that in clinical studies so far (we are not at the end of it) - we don't know yet for example what the duration of protection induced by a single dose of vaccine - the earliest data that we have indicates that at least in adults and in adolescents, one dose is sufficient, so in young children in special groups it is probable that two doses would be needed. Not all vaccines have been tested but generally it is likely to be one dose.

**Gregory Hartl:** Thank you very much so the next question will be from Elizabeth Sukkar. Go ahead please.

**Sukkar:** Hello. It is to do with the regulatory process to approve the vaccines, the US versus the EU, do they use similar application processes and secondly recently in Australia the CSL vaccines were approved there for an age group of ten years and over strangely the US FDA approved the same vaccines for eighteen years and upwards, so I was just wondering if you can comment on those two new questions?

**Kieny:** So now all countries have slightly different regulatory pathways as you know. So the vaccines which have been licensed so far by the US FDA have been licensed on the basis of a strain change, which is that they were considered as seasonal vaccines with a different strain which is a pandemic one. Therefore in the US the vaccines have obtained the licensing indications so for the population for which these vaccines are licensed for seasonal flu in the US. So the vaccines where the corresponding vaccine is licensed six months to no limit of age, this is the indication that the pandemic vaccine will get into the US, because it is a strain change. In Europe where there is not this procedure of strain change, there are two procedures in place, one is the mock-up dossier which is to register vaccines which are similar and which are made out of a model which was the H5N1 vaccine prototype, and other vaccines will take a little bit longer because they will have to undergo a full regulatory approval. In Australia they have their own way of licensing vaccines; the producer could come with clinical trial results in the population covering the indication that was given. So yes it is the case that all the products are different and also that all the pathways or most pathways where the regulators are different and therefore this is why the vaccines get different indications.

**Hartl:** Thank you the next question is from Mr Gold of Deutsche Presseagentur in Geneva, go ahead please.

**Gold**: I just wanted to ask about this issue of donations to the developing world and if you could be a bit more specific about what exactly, what amounts you will be expecting the developing world to receive and secondly you said that it would be up to the governments to decide how to distribute that, do you have any concerns that certain governments might not distribute the vaccines to the most vulnerable populations and might do it on a favouritism basis?

**Kieny:** Well we hope not! The governments are usually very responsible for that, one of the strict recommendations that we have is that it is used for health workers so that is really an important recommendation that we give to these governments. One other important factor before we deliver the vaccine: we need to have an assessment of the readiness of a country to distribute the vaccine and the readiness will include, of course, having a plan and having identified the target groups and we will review all this with the government before we send the vaccines, because nobody wants the vaccines to be sent and to stay in a warehouse for months or go wasted, even worse! So therefore one of the important factors that will help us define at what time point a particular county receives vaccines is the readiness and as I said we need to identify the priority groups because if we need to target health workers or pregnant women or children these are completely different strategies that we need to put in place to be sure that we reach the maximum number of this type of category of people. So we are really confident that the vaccine will be put to good use.

I didn’t respond to the beginning of your question, sorry. The number of doses, as I said we have currently access to 150 million doses through the manufacturers. With the calculation of what we know of what the countries who are willing to give us 10% of their own supply have purchased on their own, we know that from this we are likely to receive 50 more million doses, so that this would get us to 200 million doses. We hear and we are in contact with other governments who are willing to do something also to support this effort so this quantity is very likely to increase and we will try our best with funds raised by sister UN Organizations to be able to purchase what will be missing to allow us to deliver up to 10% in each of the countries.

**Hartl:** Thank you very much, so just a reminder to those listening if you would like to ask a question dial 01 on your key pad to enter the queue. The next question is from Helen Branswell of Canadian Press, go ahead please.

**Branswell:** You said that at this point you think that the estimate is more likely to be three billion doses over twelve months. Does that number hold if manufactures resume making seasonal flu vaccines for the Southern and Northern Hemisphere?

**Kieny:** Well this is what we factored in in decreasing from five billion to three billion. We don’t know for the time being exactly how many vaccines will need to be produced for the seasonal immunization and there haven't been any WHO recommendations on the formulation of the seasonal vaccine. So you may have seen that the Melbourne expert meeting this week has made a recommendation of the composition, not on the formulation, of seasonal vaccination of the Southern Hemisphere and that the pandemic strain is among the strain identified. So this and whether the pandemic strain is introduced in the seasonal vaccine or is kept as a stand-alone will have an impact on the number of doses so we will - this is an estimate for the time being and we will try our best in October to refine it as I said based on real data.

**Hartl:** Thank you very much, the next question is from Mr Mackmillen, go ahead please.

**Mackmillen**: I comment that it would be ideal to vaccinate the entire population at the same time but that would not be possible, what could possibly be the drawback in vaccinating half the world and let's say the other half not being vaccinated? I am referring to the chances of the virus becoming resistant sooner than we expected because there will be this divide between those who have the vaccination and those who do not have it.

**Kieny:** Well we hope that the whole world will have some access to vaccinations, this is certainly the commitment of the Director-General and the Secretary General of the UN, not to let a country to be without a vaccine so of course, you are right, in some countries it will be possible to vaccinate the whole population, in some other countries it will be only 10%. So will this have a role to play in the apparition of variants of drift variants, this is not sure. You know the influenza virus is unstable by nature so we know it will evolve. For the time being it hasn’t changed and the viruses circulating are still like the ones which have been isolated at the beginning. So what will happen if a virus drifts, changes, well if it doesn’t change too much the vaccine that we have now will still be efficient. If a virus drifts a lot then a new formulation of vaccine will have to be developed and produced. So we hope that the best use will be made of about three billion doses that the world will be able to produce.

**Hartl:** Thank you very much, the next question from Ms Favaro, CTV. Go ahead please.

**Favaro:** Two questions. Number one, would it have been better for the world to go with just one vaccine so that one didn’t have this difference between countries and its readiness and its testing and number two I am wondering if you are aware of this unpublished study from Canada that is linking prior seasonal flu vaccinations to an increased risk of H1N1 infection and if you have seen it and what the implications might be.

**Kieny:** So in terms of having one vaccine, of course it would make logistics easier, but there are individual manufacturers and they all make their own vaccines. There are historical reasons for this - there are all intellectual property rights reasons from time to time and regulatory reasons why they might be different. So it is like as if you have different cooks in different countries all making a choucroute, this may be different or roast beef or something and it may taste a little bit different - this is why these vaccines are also different. In terms of the Canadian study which is still unpublished of course, we have heard about it and we are of course linking with the investigators. This data for those of you who are not aware of it yet seems to indicate that having received a seasonal vaccine puts you more at risk of contacting H1N1 pandemic influenza or be infected. So we are trying to discuss with other experts and the Canadians themselves are trying to put a panel of experts together who will allow them to review their data. These investigators are well known, they are very capable but all studies can have biases - we are in contact also with investigators in other countries knowing these findings, [they] have tried they have looked in their own data in their own country whether they could find a similar observation and none of the other countries have been able to find anything like this. So the reason why this may be different in Canada and in this particular study as in other places in the world is not yet identified. It may be that it may be a study bias, it may be that something is real but certainly the WHO as well as the regulators in all these countries are looking forward to be able to see the data, to study the data and to come with a better understanding of whether this has any chance of putting people at risk, the fact that they have received the seasonal vaccination. I must say also that years and years of seasonal vaccination has not indicated that a previous vaccination has an adverse impact but again more data, much more investigation of data already collected and investigation of new data will be needed to see if this is really real.

**Hartl:** Thank you very much, next questions from Jennifer Tryon, go ahead please.

**Tryon:** You have indicated nine countries are willing to donate up to 10% of their countries supply, is Canada one of those countries and can you list the other countries.

**Kieny:** I will have a hard time to name the countries, they have been put in a press release so I don’t want to miss any one of them but I will try. The US started the movement, there is the UK, France, Norway, Brazil, Italy, New Zealand???, Switzerland and not Canada yet. We are discussing with Canada and we will see. Canada and other countries may be coming forward, maybe not on the initial list but we hope that as many as possible will come forward and will help with providing another vaccine.

**Hartl:** Thank you very much, next question is from Ms Udi from Japan.

**Udi:** I have two questions, one is concerning the early data of the clinical trial, you said for healthy adults one dose is enough, I would like to know why only one dose is enough, does that mean that some adults have some immunity for the pandemic influenza or not, and the second question is concerning the safety of the vaccine with a new type of adjuvant and produced by cell culture.

**Kieny:** Why one dose, it is true that it is a little bit striking because if everybody is naive which we would expect with a new virus and a new pandemic virus you would expect that one would need two doses - it may well be that there is enough similarity between this H1N1 virus and other H1N1 viruses which have been circulated before to make it that people are already primed, they are not immune but they have already seen something which resembles this virus and therefore they respond immediately after the first dose. It is interesting in the sense that numerous experiments have shown that immunization against the seasonal flu of last year for example did not induce any immune response that was neutralizing the pandemic virus so it seems to function in one direction and maybe not in the other one.

In terms of safety, the safety of seasonal vaccine without adjuvants has been demonstrated in millions and millions of people in all types of populations from 6 months to old people, pregnant women. In fact it is recommended for pregnant women. So this is one thing, the other vaccines which use adjuvants are newer there is no doubt that the safety data base is not as large, nevertheless the safety data base with one of the adjuvant vaccines, the one from Novartis includes 40 million individuals, usually elderly people but still it is quite a large safety date base. The safety data base with the other adjuvanted vaccines - the one from GSK - also includes tens of thousands of people - is not that high, it hasn't been tested or evaluated in special groups of the population.

We have currently no reason to think that they will not be safe. We had an expert consultation on this topic in June, and the experts' opinion was that, in all likelihood, these vaccines will be very safe.

**David Brown, *The Washington Post:*** Can you give an estimate of how many countries are going to be dependent on WHO for their supply of vaccines and what 10% of that total population, the summed population of those countries is?

**Dr Marie-Paule Kieny:** We estimate that the population that will be dependent on WHO is about 3 billion people, and this is a little bit more than 90 countries. Therefore, 10% of these 3 billion would be 300 million doses and this is our target in terms of getting access to vaccines right now.

**Melda Albano*:*** I would like to get your spot on the fact that developing countries like the Philippines cannot totally complete their vaccination in the purchase of the H1N1 vaccines. …Prices are expected to go up because of the big demand.

**Dr Marie-Paule Kieny:** We are aware of the fact that many of the developing countries have two hurdles to get access to vaccines. The first one at the very beginning was the price of the vaccines. Of course, vaccine is expensive and some countries don't have the financial means to buy pandemic vaccine. The other one is also supply because of the limited number of doses of pandemic vaccine which can be produced in a year – this is what we discussed a bit earlier –, and therefore because a lot of countries have already placed their orders, there is no offer any more, or very little. This is exactly for this reason that WHO is looking forward with the help of the other stakeholders to provide direct access through donations to these countries of pandemic vaccine.

# Transcript of virtual press conference with Gregory Hartl, Spokesperson for H1N1, and Dr Marie-Paule Kieny, WHO Director of the Initiative for Vaccine Research, World Health Organization

## 30 October 2009 (updated 2 November 2009)

**GREGORY HARTL:** Welcome to the WHO's virtual press briefing. My name is Gregory Hartl. Before we go forward, can I just let you know, please, that from this week forward, we will resume weekly press briefings, they will likely be on Thursdays. But for today, it is on Friday, because as we are reviewing today, the SAGE recommendations on pandemic H1N1 vaccine. The SAGE ended yesterday and we are here with you today.

With us is Dr Marie-Paule Kieny, the director for the initiative on vaccine research at WHO Headquarters, who will let you know about the major conclusions about SAGE concerning pandemic H1N1 vaccines. Other subjects will be addressed in subsequent press briefings, starting next week, likely on Thursday, and that would be with Dr Keiji Fukuda. I will now introduce Dr Kieny, who will make her introductory remarks, and we will open it up for questions. Thank you.

**DR MARIE-PAULE KIENY:** Thank you very much. I would like to update you today, on the outcome of the meeting on SAGE, which was held this week, and of the recommendations that SAGE has provided to WHO.

SAGE have reviewed the policy recommendations that they have given in July, and has considered that the recommendations given were still appropriate, notably on the priority groups for vaccinations, and has provided a few additional recommendations.

The three main recommendations are as follows:

1. First, having reviewed the immune response induced by the licensed pandemic influenza vaccines, SAGE has recommended that one dose of vaccine is suitable for people, from 6 months of age upwards.
2. The second recommendation is that, after having looked at the safety profile of these pandemic influenza vaccines both in clinical trials and in deployment, they have concluded that the safety profile was good, and recommended that pregnant women can be immunized with any of the licensed vaccines.
3. They have looked at the potential for co-administration of seasonal and pandemic influenza vaccines and concluded that these vaccines can be injected simultaneously.

[Note: See http://www.who.int/csr/disease/swineflu/notes/briefing_20091030/en/ for the full recommendations.]

Now, let me give you some background.

SAGE stands for Strategic Advisory Group of Experts. It is the highest level advisory body to WHO on immunization and vaccine matters. SAGE is made of independent experts, selected from all over the world. All the WHO regions are represented, and they are selected for their independence and for their expertise, in all the different topics which are important when you discuss vaccines and immunizations.

Prior to be selected to SAGE, they are requested to declare any conflict of interests, and it is only upon favourable review of these potential conflicts of interests that they are actually selected as SAGE members.

At SAGE meetings, you have other stakeholders who are invited to attend and to listen to the debate. These are the main stakeholders responsible or involved in national and international immunization matters, and they represent non-governmental organizations, other health agencies, national regulatory authorities, national health authorities, as well as the industry. None of these other stakeholders is invited to participate in the policymaking and in formulation of recommendations by SAGE.

SAGE met on the 28th of October, this is two days ago, to review the current status and the current evidence related to pandemic influenza, and to pandemic influenza vaccines and immunization. This is the first full SAGE meeting that was held on this matter, since the previous meeting which was held on July 7th. As I am sure you appreciate the level of evidence which is available now, in October is much higher that what available in July, and therefore, the recommendation of SAGE at this particular meeting as much more precise than what could be said in July.

So as I said, the first recommendation is about vaccine regiment, about how many doses should be used to vaccinate against pandemic influenza. So SAGE looked at the result of clinical trials, they also looked at the national regulatory authority decisions or recommendations on the use of these vaccines, and have concluded that in view of immune response, reported in vaccinated populations, as well as of public health considerations, that one dose was appropriate to vaccinate individuals from 6 months of age.

So this includes using live attenuated vaccines, using inactivated pandemic influenza vaccine, either non-adjuvanted or adjuvanted, like those manufactures' and marketed by GSK or Novartis. So for all these vaccines, one dose for all populations.

In terms of populations less than six months of age, there is currently no indication for vaccination of these infants, and this continues of course, to be the case. SAGE has also recommended that more studies should be done, including people with immunodeficiency, in clinical trials, in order to assess what could be the best regiment for immunization of these people. So in the meantime of course these persons can be immunized and should be immunized with one dose of vaccine, potentially even with a second dose, because they usually react less well to vaccination but mainly most information is needed, on the immune response, not on safety, safety has been deemed appropriate.

The second important recommendation is about safety and safety of use in pregnant women. So SAGE reviewed the results of clinical trials. Currently, there has been several thousands of persons involved in clinical trials of pandemic vaccines, and also no more than several hundred thousands of people who have been vaccinated in real field operation by deployment of vaccines organized now by 14 countries.

So all the reports received today, following vaccinations either in clinical trials or in mass vaccination campaigns, have shown that the safety profile of these pandemic vaccines is good, and is very similar to the ones which is known for seasonal influenza vaccines. Nothing special in terms of adverse events has been noted. Therefore SAGE has considered that in view of the particular importance to vaccinate pregnant women which are a significant higher risk of severe adverse outcome following infection with a pandemic virus, especially in the second and third trimester of their pregnancy, that these women can be vaccinated with any of the currently licensed vaccines, licensed by a functional regulatory authority, unless this national authority has made them a specific contra-indication for use of any specific product.

The third area where SAGE has made recommendation is about co-administration of seasonal and pandemic vaccine. As you know in certain population, currently, you have two types of administration of influenza vaccine going on. One is with seasonal vaccine, to protect the population against the seasonal strain, which is still circulating in certain areas. And the other one, which is meant to protect them against the pandemic influenza.

So SAGE has looked again at all the data which is existing, and has recommended that in the vast majority of cases, it is safe and indicated that these vaccines be co-administered, which is that, they can be administered simultaneously.

So what is the exception? The exception would be, when both vaccines are of a live-attenuated type, which is the vaccines which are administered not by injection but by nasal spray, and these vaccines should not be co-administered as indicated by national regulatory authorities.

Finally, to conclude, I would like to sum up.

SAGE has recommended that one dose of vaccine can be used for all populations older than six months of age. It has also concluded that pandemic vaccines are safe and can be used in pregnant women. And this applies both to inactivated adjuvanted and non-adjuvanted vaccines, as well as to live attenuated vaccines. And they have also recommended that seasonal and pandemic vaccines can be administered simultaneously.

With this, I would like to end my introduction and will be very happy to respond to your questions.

**GREGORY HARTL:** Dr Kieny, thank you very much. Before we go over to questions, may I remind the listeners that an audio file of Dr Kieny's briefing will be available immediately afterwards, on the WHO web site and a transcript will be available later today. So with that, can we go to the first question?

**HELEN BROWNSWELL, CANADIAN PRESS:** My first question is with regards to recommendations for one dose for everyone 6 months and upward. I think a very few data regarding efficacy of this vaccine, and children as young as 6 months. Is this data based, or is reflection of the fact that it will be best, given that supplies are limited, that the priming children that young, might be useful and might cut disease but you may not prevent disease in those kids.

**DR KIENY:** So you are right that actually the data available from clinical trials in very young children is still limited. Nevertheless, the results which are available indicate that these children do mount an immune response following vaccination with pandemic influenza vaccine. So, as you may know, SAGE has not recommended universal vaccination, but has recommended that countries consider which groups should be prioritized according to their own needs and conditions.

So the recommendation of SAGE is when children are among the groups that country wants to immunize, it is important to immunize as many children as possible because when they are considered this priority, and therefore, SAGE considered that the first priority in this case when children are targeted should be to immunize as many children as possible with at least one dose.

**HELEN BROWSWELL, CANADIAN PRESS:** OK, if I could ask a follow-up regarding pregnant women. Again, the recommendation is not based on new data per se, is it? Is it based on the fact that the places where it is being adjuvanted H1N1 vaccines is being administered to pregnant women, there has been anything seen that would raise a red flag?

**DR KIENY:** Well this is based on the fact that the safety profile of adjuvanted vaccines and non-adjuvanted vaccines are very similar, and the fact that the non-adjuvanted vaccines have been recommended for pregnant women for many many years. So there is no reason in SAGE view to distinguish between both types of vaccines. In addition, as I am sure you know, inactivated adjuvanted vaccines have been licensed for pregnant women by the corresponding regulatory authority.

**FRANK JORDANS, ASSOCIATED PRESS:** Dr Kieny, I would like ask you about the fact that in some countries, there seem to be two-tier vaccine policies going on. A lot has been said, last week, and in Germany, for example, when it transpired that the government had bought one type of vaccine for senior politicians and soldiers and another type for the general population. Did the SAGE group say anything about the consistency of vaccine administration in a single country, and which of those two vaccines would be better?

**DR KIENY:** Well, the SAGE has not deemed appropriate to make any difference between the vaccines which have been licensed by functional regulatory authorities so far, so there may be many reasons why a country may have ordered different types of vaccines. Would it be only not to be reliant on a single delivery? So we know of many countries who are acquiring more than one type of vaccine. And then you need to take decision on which group you vaccinate with which vaccine. You can say also that adjuvanted vaccines have been shown to induce higher immune response quite often than non-adjuvanted vaccines, and therefore using in certain populations an adjuvanted vaccine which is likely to also confer a broader protection with potentially drifted or mutated strains, may be of the advantage of that population.

**ALINE GOBY, CANADIAN BROADCASTING CORPORATION:** Thank you very much. I understood what you said about the safety of all vaccines adjuvanted or not, but to make it really clear, it is just that we see from the wire from ASP, in Geneva, exactly where you are, Switzerland decided that the adjuvant AS03, used by GSK, is not approved in the vaccine pandemerics for pregnant women, children aged 18 and less, and adults of more than 60 years old. And in the US, it's the same thing. The adjuvant vaccine has not been approved. So I suppose you looked when you did your survey into the experience of those countries and their expertise so could expand more on the examination you have done on this question?

**DR KIENY:** well the type of vaccines that get licensed and the indication is of course national prerogative, a need each national regulatory authority sees this in the light of a particular country situation. So, this is why, as you have rightly pointed out, for the same vaccine, different regulatory authorities have made different decisions. The EMEA, in Europe, has licensed these adjuvanted vaccines for use in pregnancy.

These vaccines were not submitted so far for licensing in the US so it is not that the US has not licensed them, they have not considered the license yet. In Switzerland recently, the Swiss authorities took another decision. Again this is in view of their particular situation and it is really in view of trying to sum up and come with a recommendation that could be more global that SAGE has looked at the safety results of this vaccine and compared them with what is known of seasonal vaccine, and has really recommended that in its view there is no reason to favour one vaccine as compared to the other for all these groups and in particular for pregnant women.

**GREGORY HARTL:** Dr Kieny, thank you very much. The next question is from Martin Enserink of Science Magazine. Go ahead please.

**MARTIN ENSERINK:** Hello, and thank you for taking my question. The EMEA last week repeated its statement from September that there is not enough evidence to recommend just one dose, so essentially they seem to be sticking to a two-dose recommendation. So countries now have two different sets of recommendations. I wonder how they should deal with that. And is SAGE saying with this statement that it is […] not to use a double dose? Is there anything against it, according to SAGE? Is there any reason why countries should not do it?

**DR MARIE-PAULE KIENY**: Well, in terms of, if you look at the statement issued by EMEA you will see that EMEA says that for the time being because they have not had the opportunity to review enough data, in their opinion, that they are still sticking to the recommendation that two doses would be preferable. But when you read the statement a little bit down the line, it also said that the information which is available now to them seems to indicate that for the Novartis and GSK vaccine, one dose seems to be sufficient. So we are waiting to see when and whether of course, but when also the EMEA will change their decision on these particular two vaccines. So in terms of whether a booster would be welcome or not, I would say what SAGE says is that one dose is sufficient. These vaccines are very safe so there is nothing against giving a booster, certainly in terms of safety but also in terms of the scarcity of this vaccine right now. You can also take the other option and say that the second dose could be used to vaccinate another person.

**GREGORY HARTL:** Dr Kieny, thank you very much. The next question is from Jonathan Linn from Reuters. Go ahead please.

**JONATHAN LINN:** I have two questions if possible. I would like to hear your thoughts about the long-term supply of flu vaccines given that so many people are now coming in and producing it, and the price is coming down and there was over-capacity in the sector before which pushed many companies to get out of flu production. Are you worried about a boom-and-bust cycle? Secondly, when you look at the supply problems that you are seeing in the United States, whether you think that the US government has made a mistake by insisting on the unadjuvanted vaccines when the rest of the world is using adjuvants and getting a lot more bang for their buck at the moment. I have a third one. Ukraine has closed schools apparently and banned all public events today on restricting people's movements round the country after getting their first deaths of swine flu. Would you have any comment on that?

**Dr Marie-Paule Kieny**: So this is a question with many hidden questions actually. I do not pretend that I will be able to respond completely to all of them today so in terms of the flu vaccine market, it is true that the global capacity has increased very substantially from somewhere around 300 million doses of trivalent vaccine to nearly a billion doses right now. So this is clearly a surge capacity in terms of seasonal vaccine update. It is still not enough in terms of capacity to make a pandemic vaccine when pandemic vaccine is needed, which is as you know every number of decades. So how the situation will evolve after the pandemic is over still is an unknown but certainly we will see a push to try and maintain this capacity by having more countries take on seasonal vaccination for their population, at least for the people who are at highest risk for severe outcomes with seasonal flu, and also we will be seeing in the coming years some new technologies coming on the market and with these new technologies it is likely that the surge capacity, which is the capacity to produce more vaccine when needed, when you have a pandemic will be better than what we have currently with vaccines produced on eggs where surge capacity is limited.

Now, it terms of availability of vaccine where the US has chosen for the time being to use non-adjuvanted but also live attenuated vaccine, which has a lot of advantages in terms of number of doses that you can make by eggs. This is a situation which may evolve as the US national authority will review more requests for marketing authorization of adjuvanted products, and we will see in the coming years how this will result. So, finally about Ukraine. There is and there has been a statement by WHO that in certain circumstances closure of schools may have a positive effect in reducing the speed of transmission of the virus and it is indeed a national prerogative to decide whether in these particular circumstances right now of the epidemic in the country it is indeed appropriate to close schools as has been done by many other countries before.

**GREGORY HARTL:** Dr Kieny, thank you very much. Next question is from Richard Knox of NPR. Richard, go ahead.

**RICHARD KNOX:** I just want to be very clear of what you are saying about the number of doses needed in children under 10. Are you saying that the SAGE Committee believes that one dose of unadjuvented vaccine is sufficient even in children under 10, and so therefore children of that age who have already received one, do not need a second? And secondly, what do the data say, as limited as they are, on the immunogencity of one dose of vaccine in these younger children? Do they appear to be equivalent […] or less than equivalent?

**DR MARIE-PAULE KIENY:** So, as you rightly point out for the time being, the data which are available are not very many, and the SAGE recommendation could change as more data is coming in. Nevertheless, what is known is that all these vaccines do induce a response which is a significant response in all ages of children. Do they all induce the same high level of response? No. Some induce a slightly lower immune response. Nevertheless in view of the fact that for the time being for the countries who want to carry out a very large vaccination campaign in children, some of the countries may encounter some rarity: the number of the vaccine doses that they have made may not be sufficient to provide two doses to all the children. This is why in terms of public health, SAGE has recommended for the time being that in those countries where children are on the priority list for receiving vaccines among the first group, which is not the case in all countries, priority should be given to all of them, or as many of them, one dose rather than vaccinate only half the same number of children with two doses.

**RICHARD KNOX:** Dr Kieny, the group is not seeing any difference between adjuvanted and non-adjuvanted vaccines in terms of immunogenicity in these young children. Is that right?

**Dr Marie-Paule Kieny:** It certainly seems that adjuvanted vaccines induce a high immune response but in general there is not enough data available to make a general statement.

**Gregory Hartl:** Thank you very much. The next question is from Deutsche Presse […] go ahead please.

**DEUTSCHE PRESSE:** I am confused about the age that you recommend. In your press statement today you say that SAGE recommends to give immunization to children above the age of 10 and you say that between 6 months and 10 years the data is limited. Now you just said on the phone that you recommend from the age of six. So, which is it: 6 months or 10 years?

**DR MARIE-PAULE KIENY**: You are right that actually there are two pages if you wish, or two lines in the SAGE recommendations. One concerns adults as well as adolescents. This means people starting from the age of 10. So 10 years of age and older where the data that SAGE has indicated sufficient to give them one dose. In children between six months and 10 years of age, the amount of data is less and therefore the current SAGE recommendation is that in case these children are in the priority groups, the priority should be to give them at least one dose of vaccine now and to cover as many of them as possible, provided that they are in the priority group.

**GREGORY HARTL:** Thank you very much. Next question is from Paul Ban ki Moon of Le Monde.

**PAUL BAN KI MOON:** My first question is can you give us an update of the availability of doses for developing countries to the present, and how the efforts of WHO to get those countries not forgotten have succeeded. Second, if developing countries stick to this one-dose only immunization, how do you foresee the discussions to have more doses given or sold to developing countries?

**DR MARIE-PAULE KIENY**: The WHO initiative to provide access to pandemic vaccine for developing countries is getting into an operational phase, I may say. We have, as of today, secured 156 million doses and we are looking forward to reach 200 million doses that we think will be needed to ensure that the 95 countries which have been currently been put on eligibility list that will receive vaccines donated by WHO would be able to cover at least 10% of their population. So, vaccine has been donated to WHO both by four manufactures as well as by governments who had acquired vaccines before. I must also that in addition to donating vaccines, some governments of countries are also donating syringes and needles and similar equipment as well as finances to assist with the deployment of the vaccine. The Director-General has approved the list of countries. These are developing countries all over the world. We have the first list of countries who are being contacted right now, at least 16 countries who will be the first countries to receive vaccine out of this donation and we expect that we will be able to provide vaccines to these countries up to the level of 2% of their population first during either at the end of November, or the first half of December. We are finalising all the contracts with the donors and with the donor companies and governments and hope that this delivery schedule will be possible. In line with the SAGE recommendations these developing countries are expected to immunize as a first priority the health care workers with this vaccine.

**GREGORY HARTL:** Dr Kieny, thank you very much. We will take two more questions. Next one is from Mr […] Poleliman. Go ahead please.

**MR […] POLELIMAN:** My name is […]. There are indeed different immunization strategies around the world, different countries in regard to adjuvanted and nonadjuvanted vaccines and they are causing much confusion in the population. Are you worried that these different strategies will affect total immunization achieved around the world and do you see if these decisions are in fact based on science or are they based more on psychology?

**DR MARIE-PAULE KIENY**: There is certainly a lot of disinformation around about vaccines, about safety, about regimen and I can only encourage everybody and you, who are responsible and whose main function is to advise and to inform the public, to look at our website. We keep it up to date and you will find the latest information on safety and the latest recommendations on WHO. We are aware of the confusion that some statements can cause and we will try as much as possible to provide accurate information to the public and to yourselves.

**GREGORY HARTL:** Dr Kieny, thank you. The last question is from CNN. Go ahead please.

**CNN:** I am going to yield to the next person.

**GREGORY HARTL:** Do we have one more question? If not, I would like to say thank you very much for today. This has been the virtual press briefing from WHO Headquarters with Dr Marie-Paule Kieny, the Director for the initiative of vaccine research.

Can I remind you please that there will be an audio file going out very shortly on the web site, and later today a transcript of this briefing. The web site is www.who.int. The next virtual press briefing should be next Thursday. Thank you to everyone. Good day.

# Transcript of virtual press conference with Gregory Hartl, spokesperson for pandemic (H1N1) 2009, and Dr Keiji Fukuda, Special Adviser to the Director-General on Pandemic Influenza，World Health Organization

## 5 November 2009

**Gregory Hartl:** Welcome to the World Health Organization speaking from Geneva, Switzerland. This is our weekly virtual press briefing. They will now come to you in future at this time, which is one o'clock in the afternoon, Geneva time on Thursdays and this Thursday I have the pleasure of welcoming Dr Keiji Fukuda, the Special Adviser to the Director-General on Pandemic Influenza who will make opening remarks and then we will open this to questions.  Dr Fukuda please.

**Dr Keiji Fukuda:** Thank you, Gregory. Welcome everybody. Thank you for tuning in to this virtual press conference. What I am going to do is what we did in the earlier virtual press conferences held at the beginning of the pandemic which was to give you an update on the situation. Today I will give you a somewhat longer update than normal since it has been quite a while since we have last spoken with you and then as usual will turn it over to questions.

In today's press conference there are two things that I want to broadly cover. One of them is simply where are we? What is the assessment of the pandemic to date and then the second issue is that I would like to talk about vaccines and really focus on some of the key things which are important for you and everybody to know.

If we look at the pandemic right now it is clear that the pandemic virus has become the dominant influenza virus in all countries. In the southern hemisphere we have now seen that activity has tailed off although there may be some pockets of activity in some countries but in the northern hemisphere we clearly are seeing that infections are picking up in a number of different countries and we will go into a little bit more detail. What this means is that we anticipate seeing continued or increased activity during the winter period in the northern hemisphere. This also means that we expect to see continued reports of serious cases coming out of countries and deaths.

Now, one of the basic points is that I want to point out that we are not dealing with seasonal influenza. I think there is a lot of confusion and a lot of comparisons made but this is one of the basic points. There are some features with this pandemic that we are seeing which are similar to seasonal influenza. For example, we are seeing that the pandemic virus is about as transmissible and about as infectious as seasonal influenza viruses is to people. We are seeing that the majority of people who get infected in fact develop a self-limited illness and get better without any special medical interventions. We are also seeing a pattern where the disease activity is higher in the winter. This is what we often see with seasonal influenza and these are more regular parts of influenza as a general disease but there are also some features which are clearly different.

For example, in the northern hemisphere we saw activity continue at high levels in several different countries during the summer months. This is unusual for influenza. Perhaps most importantly, we are seeing a pattern in which many of the serious illnesses and deaths are concentrated in people younger than 65. Again, this is a very different pattern than we normally we see with seasonal influenza.

So let me amplify on this a little bit. We are now about seven months into the pandemic and we have gone through quite an active period during the summer of the northern hemisphere and in the winter of the southern hemisphere. During the past several months we have seen that the virus has rapidly spread to virtually all countries in the world. We have now have laboratory confirmed cases in most countries in the world. We have also seen however that the experiences vary quite widely from country to country, with the experiences being relatively mild in some countries and then quite difficult in other countries. Now on the verge of the winter period in the northern hemisphere, in different parts of the world we are seeing the activity pick up.

So, for example if we look at North America we see that the activity began there quite early, really towards the early part of the fall and has continued to increase and remains at high levels in North America. So, for example in Mexico in the period since September to now, they have seen more pandemic influenza cases than they saw in the preceding months after the pandemic started in April. In the United States they are reporting high levels of influenza-like illness activity which is how it frequently followed at levels higher than in many other previous years.

Now, if we switch our attention to Europe and Central and Western Asia again we see that activity is picking up in that region. I think a good example is the Ukraine. This is a country which has received a lot of attention in the last few days and clearly they are seeing high levels of infection go on in that country. The numbers are being updated by the Ministry and so we continue to work very closely with the government there to try to provide all support which is possible.

In East Asia again we seeing that activity is picking up, a good example is what we are seeing in Mongolia which has reported a number of cases over the past week or so. Again we are working closely with the government there to monitor what is going on. Interestingly, East Asia is one of the parts of the world where seasonal influenza viruses have remained in a reasonably high circulation. These are the H3N2 viruses which have remained in fairly high circulation but as we head into the winter, even in that part of the world the pandemic virus is clearly becoming dominant and so we are seeing it crowd out the H3N2 viruses and these are really falling down in terms of the overall proportion.

Now if we look at other parts of the northern hemisphere, such as the Caribbean, again, we are seeing that cases are being reported from a number of countries such as Cuba and Haiti. Then, if look and move our attention a little more towards Central America and the southern hemisphere, now we begin to see that the activity levels have really gone down as they have moved from the winter period into the southern hemisphere summer period.

Now, let's turn our attention to some of the clinical features which have been seen over the past seven months. Now as I mentioned in the beginning most of the infections result in self limited illness so this means that when people get infected, they may develop fever, body aches, coughs or sore throat but they generally get better without the need for specialised medical attention and they do not have chronic problems afterwards. Now, this fact that most people recover from the illness has led some people to speculate that this is really a very mild situation and really do dismiss the pandemic infection but at WHO we remain quite concerned about the patterns that we are seeing, particularly again, because a sizeable number of people do develop serious complications and death and again we are seeing most of these occur in people who are younger than 65 years - a picture which is different from seasonal influenza. Now, as more studies come in, as more information comes in, the picture continues to evolve about which groups are at most risk for different outcomes and we will follow along. But, I think that the important point here is that we do see that the serious complications are concentrated in younger age groups rather than in the older age groups.

We see these complications occur in people who have chronic underlying medical conditions, we see these occurring in certain groups of people, such as pregnant women but we also see these complications can occur in people who are perfectly healthy and are young.

Based on the current picture, I think that one of things that is prudent to do is not over simplify the disease or the situation. I think what the reality is that we are dealing with two pretty different groups of people when they get infected. One is the group of people whose infection gets better pretty quickly and they don't have a problem but there is another group of people who develop quite serious disease and this can result in death. We are finding that in some countries that the numbers of people who develop serious illnesses can put considerable pressure on intensive care units and require high levels of care. So again this is an important point for people working on health systems to take into account in their planning.

In terms of the virus, so far we see that the viruses being isolated now are generally similar to the viruses which were isolated over the past several months. This is true in places such as the Ukraine, this is true in places such as the more recent outbreaks that we are seeing in the northern hemisphere. Now, because these are influenza viruses and because more people will eventually develop immunity against these viruses, we do expect to see these viruses begin to change over time. But, at least at this time right now, these viruses remain fairly stable in terms of the genetics and in terms of their antigenic properties.

Now, one of the things that we closely monitored is whether we see any antiviral resistance to the drugs currently available in these viruses. As we have discussed in the past, we continue to see sporadic cases or sporadic instances where these viruses may be resistant to oseltamivir which is one of the main drugs which is useful against this infection. However, we see no evidence at all that there is widespread occurrence of antiviral resistance and these remain really quite isolated and infrequent occurrences and so right now, we believe that the antiviral drugs are quite useful against these infections and that these viruses remain sensitive to both oseltamivir and zanamivir.

Now at this point I want to switch from a description of what is going on and move on a little bit to what are some of the things that people can do to protect themselves. This is really the most basic question when you are facing a new disease situation. The first thing I want to do is point out that there are many things that people can do which do not have anything to do with hospitals, drugs or vaccines. First and most important, is that it is really prudent to keep yourself informed, both for yourself and for your family. This is really critical but we also recognise this is at a time now when there are a lot of different voices talking about pandemic influenza. There is a lot of conflicting information out there and this is really proving confusing to many people so I think one of the important things to point out is that when you are looking for information about pandemic influenza, it is really helpful to rely on sources that you know to be credible. Sources that are informed, sources that are experienced and sources that can really provide you with the best up to date information. I think this is one of the most useful things to do to reduce confusion about what the situation is.

Now the second thing is that there are several things that people can do if they are sick. For example, if you become ill one of the basic things to do is simply to stay at home until you get better. This is both good for you, this is both protective for the people around you and will reduce the chances that you will spread infection to others but it will also make sure that you are getting some attentive care at home. There are things to do when you are around people. One of the basic things to do is something called respiratory etiquette. This means that when you cough it is prudent to cover your mouth; if you can do that using your sleeves that would be very good. If you have to cough into your hands it is important to wash your hands. If you know that your hands have not been washed recently or may have some virus on them, it is prudent to avoid touching your eyes or nose and infecting yourself. These are some of the basic steps that you can take.

Another third basic point is that if you are taking care of somebody who is sick, you should understand that the vast chances are that they are going to get better and they just need some supportive care, and being around providing them with whatever attention is needed. There are certain some things to be on the lookout for. If somebody has a fever which keeps getting higher, which goes past three days or is causing the person a lot of distress, if the person is having trouble breathing, if the person has any trouble staying conscious or awake, these are signs that perhaps the illness is getting worse and that it would be a good thing to contact a health care provider at that point.

The fourth and last point that I want to make is that if you are a person who has an underlying medical condition or you are a pregnant woman and you feel that you are getting sick from pandemic influenza, then it would be prudent again to contact a health provider and seek advice. It may that you should be seen, it may be that you need to be on antiviral drugs but these are steps that you can take to help protect yourself.

Now at this point I want to turn to vaccines and really to help provide some clarity on an area which is of high attention right now. First I want to start off making two basic points. One of them is that WHO, along with other public health authorities believe that these vaccines are very useful against pandemic infection and do support their use. The second point is that these vaccines now have been used in a significant number of countries, vaccination programmes have started in over 20 countries over the past several weeks and, based on this experience in which millions of people have now received vaccines, we in fact see that these vaccines are very safe. The levels of local side-effects - sore arm, redness, swelling in the arm when you get injected - are really very similar to what we see with seasonal influenza vaccines or perhaps lower. In terms of any unusual or unexpected side-effects, we have no evidence right now that these vaccines lead to such side effects and so basically, what we are seeing right now is that these vaccines are highly safe and have been received by a significant number of people without problems.

One of the most basic questions to ask about vaccines is why are these being promoted? Why are these useful? I think here the answer is relatively straightforward and simple. We are in a situation in which the world is seeing a new infection, this pandemic influenza. This is an infection which clearly can cause death or serious illness in a number of people and again particularly in people who are younger than 65 and particularly in certain groups such as pregnant women. We now have vaccines which are developed specifically against this infectious disease. These vaccines clearly can produce a good protective immune response and in fact one of the best surprises we have found to date, based on the studies done recently, is that one dose of vaccine rather than two is going to be enough for most people to develop a good immune response. This is really somewhat unexpected but very welcome news.

So the third point, as I point out is that we now have good evidence based on many people receiving the vaccines, but have no picture of unusual side effects emerging. Also, the side effects which are expected, such as a painful injection site, or perhaps some swelling at the injection site, these are occurring at rates that are expected and usually seen with seasonal influenza vaccine. So the picture right now looks quite good in terms of the safety.

Now one of the issues being addressed in some countries, where vaccination programmes have started, the vaccine authorities are trying to do this in a step-wise manner and focusing on certain groups first. One of the groups in whom immunization programmes are targeting are healthcare workers for the very fact that these are the people who take care of everybody else who is sick, whether with pandemic influenza, or other diseases such as heart attack, or asthma or whatever. So these vaccination programmes are trying to make sure that health systems continue to be able to do that job.

Secondly, these immunization programmes are also targeting people who are at higher risk than other people for developing series complications. So I think that if you are in a country in which vaccination programmes are being conducted it would be useful if you take these attempts at approaching vaccination in a step-wise manner into your considerations and really work with your immunization authorities so that these proceed in a way which reduces I think stress and panic at the vaccination places.

Now a final point that I want to make about vaccines is that we are in a situation in which some countries have vaccine available and other countries do not. WHO has been working very closely with both a number of countries as well as with the pharmaceutical industry to free up as much vaccine as possible, to provide vaccine to countries which would not be able to get it in any other way. So right now, based on the pledges provided by 11 countries and by four vaccine manufacturers we anticipate that WHO will be able to receive about 200 million doses of vaccines to go to about 95 countries which are countries which otherwise would not receive vaccine unless this type of assistance were provided. I want to point out that none of this vaccine has arrived yet, we continue to work very closely with the donor countries and the companies to get the vaccine out to the recipient countries as quickly as possible.

Now the last point that I want to brief you on before we open it up to questions, is that in our last virtual press conference which was conducted last week, by Dr Marie-Paule Kieny, we focused on some of the recommendations made by the SAGE group, this is the Strategic Advisory Group of Experts on immunization, and this is a group that WHO relies upon for advice in terms of immunization policy. So I just wanted to again reemphasize some of the points that were made by the SAGE committee which I think are quite important.

The first point, is that SAGE recommended that one dose of vaccine should be adequate for people who are 10 years of age and above, so adolescents who are 10 years of age and above, and adults. So this really reflects the newer information that has become available over the last several weeks, that one dose of vaccine in this age group really should provide a good immunological boost which should be protective for people.

Another recommendation made by SAGE is that for children six months to nine years, that at least one dose of H1N1 vaccine should be used when countries consider this group to be a priority group for their vaccination programs. Now here the considerations are somewhat more complicated and a little bit different than with the older age group. One of them is that we know that there is less immunogenicity data on children who are six months to nine years of age. We also know that overall supplies of H1N1 vaccine are generally limited. So after extensive discussion, what the SAGE considered was that because of these considerations that it would be better to provide one dose of vaccine to as many children as possible rather than provide two doses of vaccine to fewer children. We are mindful that more information will be coming out over the next few to several weeks as some of the studies results come out and it is possible that some of the recommendations would change and would adapt as more information becomes available. So this is some of the basis for this recommendation. So I want to point out that this recommendation does not limit vaccination of children to one dose. It may be that for some specific products, and it may be that for some of the regulatory agencies, they may point out that two doses are better for one product than one dose. In those instances, countries should follow those recommendations.

So this piece of information is a little bit complicated but it is available on the WHO website and you can go there to look for some of the details. With that I will stop the overview and then open it up for questions. Thank you.

**Gregory Hartl:** Dr Fukuda, thank you very much. Quickly to remind, an audio file of this briefing will be immediately after the briefing is over and later in the day we will have a written transcript posted on the website.

So now over to the first question…and it is from Helen Branswell, Canadian Press.

**Helen Branswell, CP:** Thank you very much. If I can ask just a couple of questions. Keiji you mention that the virus from the Ukraine don't appear to be different. From a distance it seems like something qualitatively different is happening there. Is it something related to conditions on the ground, like local health care, or might it have something to do with how the virus acts in colder temperatures, which is something the northern hemisphere is really looking out for?

My other question. Norway says it's going to be making oseltamivir available over the counter. Is that a good idea?

**Dr Keiji Fukuda:** Thank you Helen. Let me clarify on the viruses first. Right now we know that many clinical specimens and viruses have been sent to one of the WHO collaborating centres for further study. We don't know the results of those studies, and it will probably take a couple of days for the full analysis of those viruses to be available. But in the meantime, what we do not have is any evidence of viruses there or anywhere else as showing any big mutations. I raise this point because I have seen in some media reports that there are reports that WHO or other groups are saying that there are mutations and I want to point out that these are rumours and factually, untrue.

In terms what we are seeing in the Ukraine, again I think that we simply have to understand that influenza is an infection which can cause outbreaks in very large numbers of people. I mean the pandemic is an example of the ultimate kind of outbreak in which we see virus spread around the world in countries such as the Ukraine. And we are seeing very large numbers of people but I think that this is the pattern we often expect to see with influenza. I am not sure that we are going to point out to anyone factor as to why some countries have larger outbreaks than others. But it is true that we often see that patterns can be quite different from country to country.

Now in terms of your question about Norway, we have been in close contact with the Norwegian authorities both to find out about the situation in the country, and to discuss whether there is anything that WHO can offer to them. One of the interesting things which the Norwegians are doing is to make antiviral drugs more easily available for a limited period of time. The reasons that they are doing this is that the stress on the primary health care system is quite high, and that in looking at the experience in some of the other countries in making the antiviral more available it really can help facilitate both patients getting to the antiviral drugs more quickly. Also, it can also reduce the pressure being seen in the health care system.

So I think, overall, this is really an innovative and prudent move to try to make sure that the health system remains as unstressed as possible. I think that one of the underlying concerns is whether this should facilitate, or could facilitate the emergence of antiviral drug resistance, but most of the cases of antiviral drug resistance that we are seeing, in the sporadic cases, really have to do with prophylaxis and they do not have to do with treatment. And so this is really to access antiviral drugs to people who are sick. It seems to be quite an innovative move and would not seem to pose a particular danger to the emergence of antiviral resistance.

**Gregory Hartl:** Thank you Dr Fukuda. Before we take the next question could I remind our listeners that if you would like to ask a question please dial 01 to get into the queue. The next question is from Mr Richard Knox, National Public Radio.

**Mr Richard Knox, NPR:** Dr Fukuda, could you tell whether WHO and its consultants are trying to estimate when the pandemic flu will peak in specific regions, and if it is possible to do this? What the difficulties might be in estimating or projecting the peak? Secondly, how important is it to do that in terms of planning vaccine allocation.

**Dr Keiji Fukuda:** Thank you these are good questions. There are a number of different modelling groups around the world which are trying to address some of these kinds of questions. What might the future bring, what is the potential shape of outbreaks and the pandemic in general? These are important exercises because they give us potentially broad guidance on what we might expect. Overall, the major principle for planning for the next period of time, which is the winter period for the northern hemisphere, is that we have to acknowledge that we are really not going to know what the future will bring. So the main focus of our efforts here is not trying to predict what may occur in the future but what steps are needed to make sure that countries are as prepared as possible to deal with disease levels. So I think that we are looking at the winter period, and so the next several months is the period at which countries are at risk for seeing outbreaks of pandemic influenza.

Then once we get into the late winter period to spring period, we will have to reassess how the patterns are going at that time. These kinds of efforts are helpful in terms of judging what steps are needed and how to allocate resources. But it is very difficult to do on a precise level. Thank you.

**Gregory Hartl:** The next question is from Michelle Cortes of Bloomberg.

**Michelle Cortes, Bloomberg:** Thanks so much. I was wondering if you could tell us what the situation is with the production of the vaccines? I'm piggybacking a bit on Richard Knox's question that if we do see peak earlier are we going to be able to get the vaccine that we need out to the people.

**Dr Keiji Fukuda:** I believe that the disease activity and the ability to more out vaccine are probably two different things. The disease activity is very hard to predict, on a country by country basis, how things are going to go. For example, we have seen relatively fast increasing peaks in some countries coming down. In some countries, for example, the United States, activity levels go up and stay up for quite a long period of time. Regarding access to vaccine, right now we are in a situation where companies out there are producing as much vaccine as quickly as possible. Much of the vaccine has been allocated to different countries on the basis of contracts. Those facts will really effect more how countries are able to get vaccines. This is one of the reasons why WHO is working so hard with donor countries and the vaccine industry to facilitate getting as much vaccine as possible for the countries which otherwise not have vaccine available to them.

**Gregory Hartl:** The next question is from John Zaracostas of the British Medical Journal.

**John Zaracostas, BMJ:** I was wondering if you could give us an update on the availability of vaccines going out to countries. Yesterday CDC experts stressed that availability at the end of October in the United States was a fraction of what they had predicted early this year. So how far behind the initial projections are companies in the production cycle of the vaccines? Thank you.

**Dr Keiji Fukuda:** John I cannot give you detailed information on that. I do not have that information. I noticed that earlier in the overview I mentioned that vaccine has gone out to a number of countries, and vaccination programmes have started in over 20 countries, but I suspect that the availability of vaccine is a company by company issue. It is really the companies and the recipient countries that are best at providing an update on how much vaccine is going out. So it is going out right now, but that is as much as I can say at this point. Thank you.

**Gregory Hartl:** Next question, Maria Cheng from Associated Press.

**Maria Cheng, AP**: I have a couple of related questions about populations that may be more susceptible to swine flu. There were reports yesterday about the virus appearing in populations of Venezuelan indigenous groups. I was wondering if there was anything that was clinically important about that virus in terms of has it affected aboriginal groups in perhaps Australia, New Zealand at the peak? If there were special concerns you had about aboriginal groups in North America and also something related to that, I wondered if you had any indication of the impact of the virus so far in Africa, and if you knew any more about people with immunocompromised conditions, if there were things you were seeing, or recommending to officials there on how to protect those people.

**Dr Keiji Fukuda:** It is clear that there are certain groups of people who are at higher risk of developing serious illness from underlying medical conditions. So for example, as we discussed earlier, and have talked about over the past several months, groups such as pregnant women, because of the pregnancy itself are at higher risk. Also, we see that certain groups of people with different medical conditions, such as chronic lung disease, are also at higher risk of serious complications because of those conditions.

We have also seen that in some countries, that indigenous groups have been more heavily impacted than non-indigenous groups. An example is Australia, which is one of the countries in which you look at the number of people ending up in hospitals, the aboriginal groups are disproportionately represented in people who end up in hospitals from infectious disease related to the pandemic. What is not clear is whether this is due to underlying chronic conditions in those groups, whether it is due to other factors. Here the reasons for this are still not clear. I believe there are a number of groups trying to tease this out, but it is not understood yet.

However, it is clear that in some countries, some of these groups can be more susceptible to ending up in hospital for serious complications. Hopefully we will understand this better.

In terms of Africa, it is fair to say at this point, we have not seen or heard of any unusual reports of severe impact in HIV-infected populations. Again, as we go through the winter period, this is one of the most important questions that we have to keep on top of, in addition to the immunocompromised people, are there other particularly vulnerable people, or groups that we are not aware of. Could different groups become vulnerable as we go into the pandemic because of something about their condition has changed? So that about sums up the situation right now. Thank you.

**Gregory Hartl:** Next question is from Mr Liu of Xinhua in Geneva.

**Mr Liu**: Thank you Gregory. Dr Fukuda, can you say something about the situation in China. Do you think the authorities there are facing a challenging situation considering the large population in the country? How do you evaluate the government response so far to the situation there and do you have any specific recommendations?

**Dr Keiji Fukuda:** Sure, I think that all countries pose different kinds of challenges. I think that when countries are faced by situations such as pandemic influenza there are common issues which all countries have to deal with. For example, how do you get good information out to people quickly and let them know what is going on? How do you make resources available? How do you try to protect your population? So these are common issues faced by all countries. And then I think in countries such as China, where you have a very large land mass, and you also have a very large population, that these problems can be even more difficult simply because of the size you are dealing with. I think that the Chinese government, like most of the governments that I know of, have been working very hard to address the situation, and so I don't have any other particular comment on how China or any other countries dealing with it. But I do know from first hand experience with the government that they are working very hard to try to ensure that the pandemic is addressed there as well as possible. Thank you.

**Gregory Hartl:** Dr Fukuda, thank you very much. We will have time for maybe two more questions. Next one is from Martin […] of **Science magazine**.

**Martin […], Science magazine:**. Yes, hello, thank you for taking my question. Keiji, you mentioned the problems of H3N2 in Eastern Asia. I understand that a lot of that virus is the first strain which is different from the vaccine for seasonal flu. And I wonder how worrisome that is. If that virus keeps spreading do you worry that we might see a lot of additional disease on top of this pandemic virus?

**Dr Keiji Fukuda:** Thanks Martin. This is again a very interesting and somewhat difficult question to answer. First, in most countries we are now seeing that the pandemic virus is really by far the vast majority of the viruses being isolated in those countries. It has really been in East Asia where we have seen that H3N2 viruses have been in fairly broad circulation in some of the countries there. But the more recent information suggests that even in those countries that the pandemic virus is now becoming, by far, the majority virus being isolated in recent weeks. However, we do have H3N2 viruses out there and the H3N2 viruses themselves have been changing. Now there are many years in which we have a situation in which the viruses in a vaccine are not exactly matched to the viruses which are circulating, because influenza viruses are always changing themselves and modifying. In those years, you find that you really have to do the kinds of studies to determine what really is the protectiveness of the vaccine against the newly changing strains. So for the current H3N2 viruses we don't have such studies. So I can't tell you right now the degree to which the current seasonal vaccines will protect against the […] virus. I do think in the broader picture overall, again, we are seeing that the H1N1, the pandemic virus is really the majority virus in many countries. That also is an important consideration in trying to answer how much seasonal vaccine will protect people. So it's a little bit of a complicated situation. Thank you.

**Gregory Hartl:** Dr Fukuda, thank you very much. We have about five more minutes and will try to get in as many questions as we can in that time, so journalists it depends on you. The next question is from CNN. Go ahead please.

**Melissa Gray, CNN:** I presume that is for me, Melissa Gray, thank you Dr Fukuda. Quick question: Are there any countries where you are seeing a worrying rise in the number of cases; any particular regions that are of particular concern?

**Dr Keiji Fukuda:** Thank you Melissa. In the beginning when I was trying to provide an overview of what was going on around the world, I think that it is fair to say that based on that that, there are several regions in the world, North America, Europe, Northern and Central Asia, and also in other parts of Asia, where we are clearly seeing a pandemic influenza activity increase. I think that in some of the locations, such as the United States, Mexico and Canada, we have seen an early increase in activity and it has stayed up fairly high. And so we hope to see at some point it go down, but we don't see that pattern yet. In other parts of the world, such as different countries in Europe, we are seeing activity pick up more recently, and then in certain countries such as the Ukraine, we are seeing evidence of vary high levels of activity. So I think that there is no one single place in the world where we are focused on, because we are seeing that there is increasing activity going on in several different regions of the northern hemisphere. Thank you.

**Gregory Hartl:** Next Question is from Canadian Broadcasting Corporation - go ahead please.

**Derek […], CBC**: It's Derek […] here in Toronto. Thanks Dr Fukuda. I wonder if you can give me an assessment of just how effective the H1N1 vaccine is. Canadian officials say the adjuvanted vaccine that we are using here in Canada, is somewhere around 90% effective. What is your take on that?

**Dr Keiji Fukuda:** I think that the studies which are needed to actually measure the protectiveness, see how much illness and complications of pandemic reduces are being done right now. So I would love to see some of this information. But right now I don't have any study results on that effectiveness. So actually hearing these estimates from the Canadian government are actually very helpful and very useful for us. I can't add to that right now. Thank you.

**Gregory Hartl:** Dr Fukuda, thank you very much. The last question which we will take today after this reminder about the transcript and the audio file, remember on the website www.who.int. The audio file will be up immediately after the end of this briefing, and later in the day there will be a written transcript available also.

So last question is from Gabriella […]. Go ahead please.

**Gabriella […]:** Thank you. Dr Fukuda, you are talking about the pandemic viruses are the majority of the cases, but is it like 90% like in Mexico according to the declarations of the Minister of Health. Is it like this or how much is the majority?

**Dr Keiji Fukuda:** I think Gabriella that if you look at all people who are coming in with respiratory illness, what percentage of those are coming in with respiratory illness due to pandemic influenza, as opposed to other respiratory infections, varies from country to country. I think it is virtually impossible to give you a single figure for what is being seen in all countries. I can say that based on some of the laboratory data which is being provided, that when we look at the samples being collected from people, and being tested for pandemic influenza, the percentages of those samples that are positive are very high, much higher than we normally see for seasonal influenza. So based on some of the information provided to WHO, we have seen that up to about 70% of the samples being tested can be positive for pandemic influenza. But again I think it is very hard to give you a single figure, so you will see country by country estimates. Thank you…

[brief pause in the recording]

**Dr Keiji Fukuda:** …a bit more about this… just to make it a little bit clearer. In countries where surveillance is conducted, if somebody becomes sick then frequently these people will go to a health care provider. Then in a sample of these people, they will have a swab which is taken. Then the swab will get sent to a laboratory. Then if it looks like its influenza it may yet be sent on to additional laboratories, perhaps a national influenza laboratory, or perhaps one of the WHO collaborating centres. When we look at these samples we will see that some of them are positive for influenza, and that some of them are not. Now when the samples are not positive for influenza, this can be for several different reasons. It may be that the sample was collected or handled under conditions in which the virus does not survive. So it was really a positive sample but for handling reasons, the virus could not be found. It may be that the sample is handled well, but is taken at a time when the person is not infectious, so it may also be a real case but you don't find it. Or it may be that the person has another infection. Frequently we don't identify what the other infection is. Sometimes we do. So there is a variety of different reasons why you may get negative samples. But many of the laboratories around the world do follow this information. They do follow what percentage of specimens coming in is positive. In some countries, such as, in big surveillance systems, such as in the United States, you may frequently see about one-quarter of them to say about 30% of them be positive for influenza in a normal season. But right now in the United States they are seeing that over 40% of them are positive. Then as I mentioned, in some of the other countries, up to about 70% of them are positive. So this is where some of this information comes from. Thank you.

**Gregory Hartl:** So thank you very much to all of you listening. And thank you to Dr Keiji Fukuda. This has been our virtual press briefing for 5 November, and we will be here next week at the same time. Thank you very much. Good bye.

# Transcript of virtual press conference with Gregory Hartl, Spokesperson for H1N1, and Dr Nikki Shindo, Medical Officer, Global Influenza Programme, World Health Organization

## 12 November 2009

NB: there are some passages in this transcript which have not been transcribed because of poor audio quality.

**Gregory Hartl:** Good afternoon it is 1.00 o'clock in Geneva on today Thursday, 12 November and welcome to our weekly virtual press briefing. Today, I have the pleasure of bringing to you Dr Nikko Shindo, Medical Officer in our Global Influential Programme here in Geneva who will speak to you about the clinical treatment of H1N1 cases. So without further redue I hand you over to Dr Shindo who will make her opening remarks and who will open questions to you. Thank you.

**Dr Shindo**: This is the beginning of the influenza season in the Northern Hemisphere. We are seeing upsurges of pandemic influenza activity in countries across Europe and Asia. In some countries, hospitals and clinics are overwhelmed with the number of patients they are treating.

One way to save lives and to lighten the burden on healthcare systems is to prevent severe disease.

Today, I am here to talk to you about the importance of early treatment to prevent severe disease. I will also discuss what WHO is doing to help developing countries dealing with the pandemic.

When WHO first published guidelines for doctors treating patients with pandemic H1N1, we were focussing on how to TREAT severe cases. Now, with more data and experience with the disease, we have better information on how to PREVENT severe disease. WHO has now published updated clinical management guidelines. They are based on what we now know about the virus and how it affects people.

In a country where the virus is circulating, we have 3 updated recommendations.

1. Firstly, people in at-risk groups need to be treated with antivirals as soon as possible when they have flu symptoms. This includes pregnant women, children under 2 years old, and people with "underlying conditions" such as respiratory problems.
2. Secondly, people who are not from the at-risk group but who have persistent or rapidly worsening symptoms should also be treated with antivirals. These symptoms include difficulty breathing and a high fever that lasts beyond 3 days.
3. Thirdly, people who have already developed pneumonia should be given both antivirals and antibiotics, as we have seen that, in many severe cases of H1N1-caused illness, bacterial infection develops. These medicines, antivirals and antibiotics, if used in a timely manner, can help save lives.

I want to stress that people who are not from the at-risk group and who have only typical cold need not take antivirals. We are not recommending taking antivirals if otherwise-healthy people are experiencing only mild illness, or as a preventive measure in healthy people.

So, to recap, we have updated our clinical guidance to emphasize that seeking early medical attention can save lives. We have heard that, doctors involved in caring for very sick patients in intensive care units regretted that the patients arrived too late and even the most sophisticated medical procedures could not save their lives. We asked what could have been done differently to avoid the tragic outcomes. All of them answered, without exception, that things may have been very different if they had been treated with an antiviral drug earlier.

The pandemic virus can cause severe pneumonia even in healthy young people, though rather minor in proportion, and the virus can take life within a week. The window of opportunity is very narrow to reverse the progression of the disease. The medicine needs to be administered before the virus destroys the lungs.

In the initial guidance, we took a more conservative approach because we had almost no experience with regard to the effectiveness of the antiviral medicine in this disease, and also we were aware that access to the influenza medicine was very limited. Now, we have gained knowledge in effectiveness, safety of the medicine and we have also contributed to the global availability of the medicine.

I want to talk a little now about how WHO is supporting developing countries to face an upsurge in cases.

We are supporting countries with technical guidance, of which the recommendations are part. A further recommendation we make is that countries decentralize the distribution of antivirals, and ensure that general practitioners have access to these medicines for their patients. Patients should not need to visit a hospital in order to get antivirals prescribed. This should help ensure that individuals get the care they need faster, and that the burden on hospitals, is reduced. This will leave hospitals freer to treat the most severe cases.

We also recommend that where antiviral supplies are limited, countries prioritize the distribution of antivirals. This means an emphasis on early use with at-risk groups, and use to treat progressive and severe illnesses.

WHO has a stockpile of antivirals that is used to bolster the supply in resource poor countries. In May, at the beginning of the pandemic, WHO shipped antivirals to 72 countries. More recently, we sent supplies to Afghanistan, Mongolia Belarus and Ukraine, and we will soon send additional supplies to Azerbaijan and Kyrgyzstan. All our 6 Regional Offices have oseltamivir stockpiles and we will use these to support countries which are likely to be hard-hit this winter, and unable to meet their needs on their own.

WHO has also sent other supplies, such as specimen collection materials, reagents for diagnosis, personal protective equipments, antibiotics and medical equipment, such as pulse oxymeters. We will continue to work with these countries to develop strategies to fight the pandemic.

In conclusion, I would like to repeat our key message. In at-risk groups, in order to prevent progression to severe disease, antivirals need to be administered early. This also holds for otherwise-healthy people who show progressive symptoms. In addition, patients with pneumonia should also be treated immediately, with antiviral medicine, antibiotics, oxygen and balanced fluid management. At the same time, remember that the vast majority of people who have H1N1 will recover without medication or going to the hospital. However, individuals without underlying conditions also should watch for danger signs and seek medical care if worsening or if no signs of improvement in 3 days - preferably from your family doctor, who knows you best . Only then may a doctor prescribe antivirals to otherwise-healthy individuals. Do not take antivirals without the doctors advice.

Thank you very much for your attention, and now I am happy to take your questions.

**Gregory Härtl**: Dr Shindo, thank you very much for the opening remarks. Before we go to questions may I remind everyone listening that an audio transcript will be available immediately after this briefing and a written transcript will be available later in the day on the WHO website which is www.who.int. Now for journalists who want to ask questions please type 01 on your keypad to get onto the queue. The first question is from Frank Jordans of Associated Press in Geneva, go ahead please.

**Frank Jordans, AP**: Good afternoon Dr Shindo. Two questions: the first question is, you talked about some countries being overwhelmed with the number of cases thy have in their hospitals and clinics. Can you tell us which countries you are talking about here? And secondly, about the risk factors that might case otherwise cause otherwise healthy young people to get severe cases. Have you identified any more of these risk factors?

**Dr Shindo**: OK to answer your first question, we are getting reports from Ukraine, Afghanistan and Mongolia about the overwhelming number of cases of pandemic influenza. And for your second question, the risk factors for the previously healthy people to have the progressive or severe disease it is incompletely understood. It was pointed out that perhaps obesity especially morbid obesity could play a role.

**Richard Knox, NPR**: Thank you very much Dr Shindo. A couple of things. Is there enough Tamiflu, in WHO's estimation, to support these guidelines? And if shortages do develop in certain areas is as infection rates increase with cold weather, is WHO recommending prioritisation of Tamiflu within either high risk or non high-risk in people? And then I have a second question if I may.

**Dr Shindo**: To answer your questions, we are getting 5 million additional stockpile that makes in total global WHO's gobal stockpile up to 10 million treatment courses and plus some paediatric capsules. But we don't think that this is enough to meet the need of the countries. So we have been working with partners and also with other countries who have enough supplies to meet the global need. And your second question?

**Knox**: Yes, to follow on that, what do estimate the global need is under these guidelines?

**Dr Shindo**: So we calculated the at-risk groups in developing countries and population profile and perhaps they are more or less about 4% of the population of the developing countries.

**Knox**: And that translates into how many needed courses?

**Dr Shindo**: So you calculate that, it's the 6.3 billion population in the world, so …

**Knox**: Has WHO apprised CDC in the United States to this policy change? And can you tell us if CDC is goung to go along with the new treatment guidelines this time?

**Dr Shindo**: So our antiviral guidance are quite similar and we are in the same line because we have been collecting evidence globally and also we have organized a global consultation in October to collect information both from published sources and unpublished sources. So we have quite similar sources to develop these guidelines which is the evidenced based guidelines so as far as antiviral recommendation is concerned we are quite in the same line.

**Phil Serafino, Bloomberg:** Dr Shindo, I may have missed this but what has changed under the guidelines- what was the previous recommendation and what is the new part of the guidelines and I have a second question also which may not be your area of expertise but have you heard anything about the mutation of the virus or has it changed at all - are we looking at anything different than a few months ago.

**Dr Shindo**: Well, I can answer that question first. The virus is quite stable. It hasn't changed - the disease pattern did not change either. The new points about this clinical management guidelines, the reason why we are updating now is now we can more confidently say that early antiviral use make changes in terms of prevention of severe illness and death. This is one big change. And we were not sure about the safety profile of antivirals at the beginning but we have received much information about very severe illness in pregnant women and young children and we have gained experience in safety in these populations. That's why we are changing the recommendation to make it more explicit about early treatment.

**G. Hartl**: Thank you very much Dr Shindo. The next question comes from Joseph in Kuala Lumpur. Can you please give the name of your media.

**Joseph**: This is Joseph from Kuala Lumpur - I am from the Sun Media. My question has already been answered by Dr Shindo just now regarding the severity of the virus. I just want to ask whether or not any slight mutation even a drift variant has been noticed so far.

**Dr Shindo**: Amazingly this virus is very stable and part of the reason, virologists (are saying) is because of the lack of pre-existing immunity in population so that virus doesn't have to mutate to escape from people's immunity. So it's quite stable.

**Helen Branswell, Canadian Press**: Dr Shindo, I was wondering is it WHO's sense that antivirals are being insufficiently used at the current time and can you get the message out to doctors that this 48 hours rule is not sacrosanct. You are talking about treating people if they start to decline that could be outside of 48 hours and I know that in some cases doctors believe that if it's after 48 hours there is no point in administering the drug.

**Dr Shindo**: A very good point. The treatment is warranted because the effectiveness of the antivirals (foes) together with people's immunity. So if used in people in immuno-suppressive status then the doctors have to think differently for the use and as people really don't have pre-existing immunity for this virus, at any stage this medicine can be used. And regretfully many doctors reported that the treatment has been delayed because the doctors wanted to wait for the test result. They wanted to have the proof that the patients were infected by H1N1 but if the epidemiological information suggests that the virus is circulating then the doctors should not wait for the laboratory confirmation but make diagnosis based on clinical and epidemiological backgrounds and start treatment early. And for severe cases, don't worry about whether within 48 hours but in any stage of severe illness they can start treatment.

**Betsy McKay, Wall Street Journal:** Thank you very much. A couple of questions. One is about the recommendations for people who are not high risk.. One of the problems we hear from readers is they are worried that they could develop these severe symptoms when they get sick. So I'm wondering how worried you are about over use of antivirals. In other words, someone gets sick and they have a fever, they're worried, they don't want to wait three days and they try to get antivirals early. The second question - I'm wondering if you could talk a little bit more about the health care systems in Eastern Europe and Mongolia, some of the countries you mentioned. Do you feel that they are going to be able to get antivirals to some of these people in time.

**Dr Shindo**: Your first question - many countries are developing a system to answer people's questions for example developing a hotline service to answer the questions from the patients. This is very important, and in the United States they have developed a web tool so that the patient can evaluate their illness severity. That's one effort. If you cannot really decide then I would suggest to consult a medical professional to get their advice. And for your second question, the medical system - we have been very closely in touch with ministries of health and local authorities through our country offices and the regional offices and try to disseminate this important message to push out the antiviral treatment to general practitioners level so that they can prevent overwhelmed ICU or hospitals by this measure.

**G. Hartl**: Thank you very much - next question - Aline Gobel of Canadian Broadcasting Corporation.

**Aline Gobel, CBC**: Could you provide us with information on the risk factors. Who gets sick and who dies from the virus. A few months ago we were told that young people were the most target of this new virus, and now it seems that the Lancet for instance is talking about old people dying of the virus more than young people. On the same line, in Canada, we have a debate in Quebec especially on the priority for vaccination. For people with underlying medical conditions, in Quebec the vaccination is given in priority to people under 65. Does WHO recommend that all people with underlying conditions get the vaccine in priority whether they are over 65 or under 65.

**Dr Shindo**: I can give you WHO's views on this based on the information we collected globally. If you look at hospitalization rate, it is highest in the age group younger than 2 years of age. This information has been compiled from the experiences in countries in the southern hemisphere who just finished their winter. This is one group that you can expect high hospitalization. Also the second group is the pregnant women. The pregnant women is about 4-5 fold at risk of hospitalization and in severe cases it comprises about 7-10% of ICU hospitalizations. So this is the second biggest at-risk group. And the third one is the chronic medical condition, first comes the chronic lung disease group, especially chronic obstructive lung disease including asthma. So they have high probability of developing severe disease and as we collect more date from countries especially from southern hemisphere countries the risk factors become very similar to the risk factors for seasonal influenza but we still don't have many reports of severe cases in a higher or older age groups, namely over 60 years old or older. But it is true that severity shifts to the older age groups. If we talk about the case count then the highest is very young adults and children. But if you look at hospitalization, the median age is about 20-35 and then the more severe cases 35-45 so almost 10 years age shift towards the more severe cases. So that is true. In terms of the countries prioritization in vaccination, the countries have to balance what is available and how many vaccinations is available timely. None of the countries will receive all expected quantity of vaccines in a timely manner so they have to prioritize within the at-risk groups. So WHO said healthcare workers are the first priority to make sure that the health service and medical service run through the pandemic season. And the next group depending on the population and the availability of vaccines, countries have to decide whether they should go ahead with very young children or pregnant women or people with other underlying conditions.

**G. Hartl**: Thank you very much. Next question from David Brown of the Washington Post but David before you ask the question can I please remind all journalists in the queue that if you wish to ask a question, please type 01 in on the keypad of your phone. Go ahead please Dr Brown:

**David Brown, Washington Post**: Thank you. Dr Shindo, I was wondering if you could talk a little bit about the countries that you say are being overwhelmed - the ones in Eastern Europe and Central Asia - are they being overwhelmed with relatively mild cases or do they have a much larger percentage of severe cases and if it's the latter is there any explanation for this. Are these severe cases heavy smokers, undernourished people, young kids, alcoholics, is there any explanation if they are actually having a higher percentage of very severe and fatal cases.

**Dr Shindo**: I can answer based on the information we received from the Ukraine. The relatively severe cases proportion wise is less than what we heard from the southern hemisphere. It seems like a load of patients being admitted with rather milder symptoms than people requiring ICU care. And mostly the admitted people (are) young adults or middle-aged adults and we have not heard so much of paediatric patients overwhelming the paediatric wards. And from Mongolia we are hearing that pregnant women are hospitalized and over-represented.

**G. Hartl**: Thank you - next question is from an as yet unidentified journalist - could you go ahead please:

**Terry Rees**, CBC: You talk about antivirals. A lot of people are turning to the internet where they are finding various products that will boost the immune system. First off, is there any merit to using these products. What is WHO's advice to people on these sorts of things.

**Dr Shindo**: We have been collecting this kind of information but we haven't so far had enough information to recommend one of those products so currently we are asking our clinical network to evaluate and that is where we are.

**Terry Rees**: Is there any merit to doing things to boost the immune system.

**Dr Shindo**: We have been asking our clinical network to evaluate but so far we have zero product included in the current recommendation.

**G. Hartl**: Dr Shindo will make a few closing remarks - then we will wrap up if there are no more questions.,

**Dr Shindo**: Thank you Gregory. I just wanted to highlight our key message. First focus, we would like to focus on prevention of severe disease with early treatment. And WHO is supporting resource-poor countries in patient care and we will continue. The majority of people will recover without treatment. You need to consult a doctor if you have underlying conditions or persistent symptoms such as high fever and difficulty in breathing. Thank you very much.

**G. Hartl**: Dr Shindo, thank you very much. This has been our virtual press briefing for today, 12 November. As we stated earlier, there will be an audio file going up on the WHO website almost immediately and later in the day there will be a written transcript up on the website and the address is www.who.int.

Thank you very much.

# Transcript of virtual press conference with
# Dr Marie-Paule Kieny, Director, Initiative for Vaccine Research
# World Health Organization

19 November 2009

**Nyka Alexander, WHO communications officer**: Good afternoon. We welcome you to WHO's weekly virtual press conference today on 19 November, 2009. My name is Nyka Alexander. With us is Dr Marie-Paule Kieny, the Director for the Initiative for Vaccine Research at WHO. She will be providing an update on pandemic vaccine. I will now pass it over to Dr Kieny who will make her introductory remarks and then will open it up for questions. Thank you.

**Dr Marie-Paule Kieny**: Good afternoon, good morning. With pandemic flu vaccine programmes well under way in a number of countries, and beginning in others, I would like to take the opportunity to update you on the overall situation, starting with vaccine availability, and then discussing safety.

Beginning with numbers, we estimate that at least 80 million doses of vaccine have been distributed and that at least 65 million doses have been administered. These are figures that we have received from 16 countries, but we think they are conservative estimates because immunization campaigns are under way now in 40 countries.

In the developing world, where WHO will distribute the donated vaccines, we expect to start shipment at the end of this month, and to continue this distribution well into 2010.

These timelines underline the importance for people everywhere to use common sense non-clinical measures to protect themselves, such as washing hands regularly, covering sneezes and coughs, and staying home when sick. As my colleague Dr Nikki Shindo discussed last week, WHO advises health providers to focus on early treatment for at-risk people with flu or anyone showing signs of serious illness.

Given this scale of vaccine administration, at least some rare adverse events could not be excluded. I will give you details in a moment, but from what we see so far, the pandemic flu vaccine has the same safety profile as the seasonal flu vaccine. The 65 million doses administered are cumulative number across countries and regions. They include different products, inactivated with or without adjuvant as well as live attenuated vaccines. No significant difference in the safety profile between different types of vaccines has been detected to date.

How has the vaccine's safety been measured? National authorities are responsible for monitoring the results of immunization campaigns in their countries. Surveillance systems are set up to record any occurrence of illness or death in people who have been vaccinated. The national authorities have been regularly sharing their findings with WHO. So far, there have been a similar number of events reported as we would see for seasonal flu vaccine. We have seen a rate of about 1 report for 10,000 doses of vaccine. Only 5 reports out of 100 reports are for a serious event. Each instance is investigated by national authorities to see if there are any connections between the vaccination and the adverse event. Since many deaths and illnesses are expected in the general population over any given period of time from other causes, the investigations focus on finding if there is a plausible link to the vaccine. The reports are then assessed to see if the vaccine may be the cause. A small number of deaths have occurred following vaccine administration. All such deaths, reported to WHO, have been investigated by the countries. Although some investigations are still on-going, results of the completed investigations reported to WHO have ruled out that the pandemic vaccine is the cause of death.

There has been in particular a lot of concern about Guillain-Barre syndrome because of the incidences during the swine flu vaccination campaigns in 1976 in the US. To date, less than a dozen suspected cases of Guillain-Barre have been reported following vaccination. Only a few of these Guillain-Barre cases may be linked to the pandemic vaccine. Illness has been transient and patients have recovered.

What we do see is a variety of local reactions, such as pain at injection site, swelling, redness and reactions such as fever, headache, muscle pain, or fatigue. These generally resolve within one or two days. A variety of allergic reactions have also been reported.

National authorities will continue to monitor the situation closely and report their findings to WHO, and we will continue to keep you informed.

To conclude, vaccine campaigns continue worldwide. No new safety issues have been identified from reports received to date, but WHO will remain in close contact with national authorities who are monitoring for adverse events. So let me repeat, reporting so far reconfirms that the pandemic flu vaccine is as safe as seasonal flu vaccines. I would be very happy now to respond to any question you might have for me on this topic.

**Nyka Alexander:** Thank you Dr Kieny. Before we go to questions, may I remind you that an audio file of Dr Kieny's briefing will be available immediately afterwards on the WHO website and a transcript will be available later today or possibly tomorrow morning. The website is www.who.int. To ask a question, please type 01 on your type pad to get in the queue. The first question is from Jason Gale from Bloomberg. Please go ahead.

**Jason Gale:** Good morning, good evening actually Dr Kieny. I want to ask you about demand for swine flu vaccine in the countries where it is currently available. It seems to be that some people are clamouring for it and others are spurning it. To what extent is the plethora of conspiracy theories that one reads on the internet having an effect on the perceived risk of the vaccine and what is the public health implication of that? If I can ask an associated question, which of these conspiracy theories seem to be doing the most damage?

**Dr Marie-Paule Kieny:** The conspiracy theories have indeed been brought to our attention. We really think that these can be damaging and indeed there are worries which are artificial worries generated by these conspiracy theories. Really what we would like to do is that we have to reiterate that the vaccines are safe, that the disease in certain people can be severe and can be the cause of death and therefore this is not the time to discuss or try to work out whatever conspiracies there may be. This is a time to work together, to produce more, to distribute more and to protect as many people as possible against this pandemic virus.

**Nyka Alexander:** Thank you. The next question is from Stephanie at Reuters in Geneva. Please go ahead Stephanie.

**Stephanie Nebehay**: I just wondered if you have any comment on a report by Novartis the other day saying that there has been a US study suggesting that half a dose of their vaccine may be enough to give people immunity and whether you have had any other data suggesting that from some other studies or drug makers. We have a second question, if you have time, on China. Thank you.

**Dr Marie-Paule Kieny:** In terms of manufacturers coming with clinical trial results showing that half a dose could be effective, these are results that we have received from other manufacturers also. Of course, this has to be taken with some caution because the numbers are still small. It may well be the case that a smaller quantity of vaccine may be protective but it is really up to the national regulators to define what is the best regimen for immunization in their countries. As for WHO, we have already made the recommendation that currently we think that one dose of a licensed vaccine is what should be used in adults at least and that in children, because of public health reasons, it may be more important to give as many children as possible the first dose as quickly as possible in countries where children are targeted. We are really relying on regulators to give us their best advice on the best dosage.

**Nyka Alexander:** Before we go on to the second question from Reuters, I want to remind those journalists on the line that you can type in 01 on your key pad if you wish to get in queue to ask a question. Please go ahead Stephanie with your second question.

**Stephanie Nebehay**: Thank you. There was a story out of Beijing this morning by medical experts suggesting that China may have had more H1 flu deaths than have been officially reported. I wondered if you were aware of these sort of reports and whether you are convinced that authorities are in fact checking and recording correctly the causes of deaths, in other words, that they are reporting accurately to WHO.

**Dr Marie-Paule Kieny:** We think that the national authorities do report accurately to WHO. As I am sure you know, to confirm that a death has been caused by H1N1 needs some confirmation and therefore we may receive it a little bit later but we are confident that the reporting that we get is what is really happening.

**Nyka Alexander**: Do we have any more questions on the line? I will give everyone one more reminder that you dial 01 if you want to get in queue. I hear there is one more question lining up. Just a moment please - sorry about the technical difficulties. I will take this moment to remind everyone that the transcript goes up on the web but first the audio goes up. So, the audio comes first and the transcript comes a little while later. We do have a question from Eliane at AP. Eliane, you are on line. Please go ahead.

**Eliane Engeler:** Dr Kieny said that shipment of vaccines to developing countries would start at the end of the month. Can you tell us when it will arrive in those countries and which will be the first countries getting the vaccines? I wonder if there has been any delay because a few days ago WHO said that these poor countries would receive the first doses of vaccine in late November, now it seems to be a little bit later. Then I have a second question. It seems that WHO does not have a programme to vaccinate its own staff at headquarters. What is the reason for that? Would it not make sense for WHO to vaccinate its staff to make sure that they can continue working if the outbreak gets more severe here in Geneva?

**Dr Marie-Paule Kieny:** In terms of delays in the delivery date, there has indeed been a few days' delay compared to what we thought we would do. The first delivery of vaccine will go during the first month to 35 or slightly more countries and then the same amount the next month and the third month. We expect that over the next three months we will be able to deliver vaccines to the 95 countries that are eligible to receive vaccines. For the second question, the vaccination of staff in Geneva, we are particularly fortunate in Geneva that the Swiss authorities are opening a programme of vaccination for their population and this is the case also for France, the neighbouring country, so the staff of the organization will be vaccinated through operations conducted by these two governments.

**Nyka Alexander**: Thank you. The next question is from Martin Enserink from Science Magazine. Please go ahead.

**Martin Enserink:** Thank you. I was wondering about the vaccine that will go to developing countries - who decides exactly where that goes? Is it WHO or is it the donors that actually give the vaccine? I am asking because I saw a press release saying that the US would donate almost a million vaccine doses to the Ukraine in early December. Was that their own decision or was that taken in consultation with WHO?

**Dr Marie-Paule Kieny.** The decision on which vaccine goes where is taken in function of the quantity of vaccine that we have from different types and of the size of the population. We try, as much as possible, to provide only one type of vaccine per country because for logistical reasons this is easier to handle. In terms of your particular case with Ukraine, the US indeed is donating vaccines to WHO and it is WHO who will orchestrate the distribution of vaccines to these 95 countries and it remains to be determined exactly which vaccine will go to Ukraine.

**Nyka Alexander:** Thank you. Next is Rebecca Smith, Daily Telegraph. Please go ahead.

**Rebecca Smith, Daily Telegraph**: Hi thanks taking my question. Early reports in the UK is suggesting the uptake rate among the priority groups may be fairly low. Can you tell me what would be an ideal of uptake rate that countries should be aiming for to control the outbreak?

**Dr Marie-Paule Kieny**: Well, you would hope to have the maximum uptake in the population in the target groups. So if you target pregnant women, like many countries do, we would really like to have a very high uptake more than 80% going to 100% if possible. So it is worrying indeed that certain groups don't seem to be coming up readily to be vaccinated, but we hope that the data which are being recorded by all countries and by WHO also on the safety of these vaccines will dissipate the worries that populations might have and will help them convince them that vaccine is safe and that vaccination will protect them against this disease which can be severe.

**Nyka Alexander:** Question from Sharon. Next we have a question from Sharon Ottawa,

**Sharon Kirkey, Canwest News:** Dr Kieny, could you go over again the adverse reaction reports? I am wondering in particular if serious reactions what the current rates are. The Chief Public Health Officer for Canada on Tuesday said that serious reactions with our adjuvented vaccine here in Canada are less than 1 per 100,000 doses. So could you go over again, just the figures?

**Dr Marie-Paule Kieny**: So the reports that we have is one report for every 10,000 doses of vaccines. So these are all reports together and can be anything from very mild to more serverw. Now, of the reports that we get, 5 out of 100 reports are for a serious event.

**Nyka Alexander:** Sharon do you have a follow-up on that?

**Sharon Kirkey:** Sorry could you clarify what some of the most serious events are?

**Dr Marie-Paule Kieny**: Well, of course most of these serious events is death and there has been a small number of deaths. But again a report. doesn't mean that this event is linked to the vaccine or that the vaccine is the cause. But they have been investigated so the more servere event, as I say, is death and of those we have heard around 30. Then potentially Guillain-Barre but Guillain-Barre we had a dozen of which only a few can be possibly due to the vaccination. And all have resolved without sequelae. So these are types of events that we have recorded.

**Nyka Alexander:** I have one last caller on the line. I am sorry also not very many details are …. Spanish caller. Is there is somebody on the line?

**Joseph**: There seems to be a bit of confusion in certain countries in Spain at least about whether children should or should not be vaccinated. This has come after some children have died from influenza, from swine influenza. So I would like to ask you whether you can comment on the rationale for or against vaccinating children.

**Dr Marie-Paule Kieny**: Well, there is absolutely no reason not to vaccinate children. Now as we have discussed many times countries' national authorities have different strategies as to the use of the pandemic vaccines. And really they need to see what they target first, if they what they want to target first high risk groups, pregnant women or if they want to try to have an impact on spread of the pandemic and then target children first. It is really specific strategy which is adapted to each of the national situation but there is no reason not to vaccinate children. The vaccination is safe, and is safe also in children.

**Nyka Alexander:** We have a question, I believe it is the last from Blaise Lempen, ATS, in Geneva, please go ahead.

**Blaise Lempen, ATS**: Yes, thank you. Do we need to be vaccinated also against seasonal influenza and it is safe to do it simultaneously?

**Dr Marie-Paule Kieny** So this question has been reviewed also recently by the Strategic Advisory Group of Experts, the highest level advisory body on immunization at WHO and they have looked at the pros and cons of simultaneous administration and they have recommended that seasonal vaccine and pandemic vaccine can be administered together. The only case when this is not the case which should not be done, and these are really very rare cases, is when both the seasonal and pandemic are live attenuated types where they should not be co-administered. Apart from that the recommendation of WHO on seasonal vaccination haven't changed and the groups who are priotized for seasonal vaccination should continue to be vaccinated.

**Nyka Alexander:** Thank you very much. That was our last call and I would like to thank everyone today for listening into the Virtual Press Conference from the WHO headquarters with Dr Mary-Paule Kieny, the Director for the Initiative for Vaccine Research. Thank you Dr Kieny, thank you to the journalists on the line. We remind you once more that audio file will be posted on the website: www.who.int and the transcript later this evening or tomorrow morning. The next virtual press briefing will be next Thursday. Thank you to everyone and have a good day.

# Transcript of virtual press conference with
# Kristen Kelleher, Communications Officer for pandemic (H1N1) 2009, and
# Dr Keiji Fukuda, Special Adviser to the Director-General
# on Pandemic Influenza, World Health Organization
# 26 November 2009

**Kristen Kelleher**: Good afternoon. This is Kristen Kelleher speaking from the World Health Organization in Geneva, Switzerland, today on Thursday, 26 November. This is our weekly virtual press briefing. Today I have the pleasure of welcoming Dr Keiji Fukuda, the Special Adviser to the Director-General on Pandemic Influenza. Dr Fukuda will make opening remarks and then we will open up for questions. Dr Fukuda, over to you.

**Dr Keiji Fukuda:** Thank you Kristen. Welcome everybody. Thank you for attending this virtual press conference. As has been normal in our earlier press conferences, what I'll do is try to provide an overview and highlight some main subjects and throw it open for questions. So the thing I want to do is simply give an update on how the pandemic is progressing.

So currently we see that the pandemic continues to evolve, primarily in the northern hemisphere. However, overall the health and surveillance systems out there appear to be coping quite well. Now, activity remains high in a number of northern hemisphere countries and, as we have previously reported, low in the southern hemisphere. There continues to be changes in up and down activity in countries but I think that overall right now it is still too early to say whether we are seeing peaking of activity in the northern hemisphere. Again we see differences on a country by country basis but difficult to say on an overall basis. I think the take-home message here is that we need to expect to see continued activity for at least some number of weeks in the northern hemisphere before we see a definitive downward turn.

Now the second point I want to make is that we now have about seven or eight weeks experience with the pandemic vaccination programmes out there and that pandemic vaccination is proceeding with no unusual safety problems identified to date. So, right now we estimate that about 40 countries have distributed at least 100 million doses of vaccines among their populations. The rates of local side affects, such as soreness in the arm or some redness, is, as expected, about at the rates of the seasonal vaccine or perhaps even lower. We have seen that there has been some reporting of serious events in investigations of people after they have been vaccinated and in most of these investigations we have seen that the serious events are not related to the pandemic vaccine. Yesterday, the Canada Public Health Agency reported that there were six cases of anaphylaxis with one lot of pandemic vaccine. Now, as we understand, none of this vaccine was distributed outside of Canada. All of the persons who developed anaphylaxis recovered fully and did not require hospitalization. All of the unused doses of vaccine have been put on hold - that is, they are not being used at this point while investigations go on. One of the take-home messages here I think is that this is exactly how we hope for the safety surveillance to go on. This is an instance in which a problem was identified, both by the country and by the company and it was quickly acted upon. The information was gotten out and the appropriate steps were taken.

The third point that I want to make is that in the past week or so we have had some potentially important developments that I think are important to put in context and to understand. One of these has to do with two separate clusters of oseltamivir resistance identified in the UK and in the United States, again separate clusters and the second event is the reports of mutations that have received a lot of publicity in the media. So, let's first turn to the clusters of oseltamivir resistance. Towards the end of last week - let me first start here - at this current time WHO has been notified of about 75 oseltamivir resistant viruses. Now among these 75 oseltamivir resistant viruses, at the end of last we have two clusters of viruses which were reported to WHO. Now, in the United Kingdom we understand that there were nine patients in a hospital who developed pandemic illness and we understand that from five of these patients, oseltamivir resistant viruses were identified. In one of the patients the virus was sensitive and in the three other viruses the tests are still going on.

In a separate cluster in the United States we understand that there are four patients in one hospital in the United States who also developed pandemic illness while hospitalized and they also had oseltamivir resistant viruses isolated from those four patients. Now, similar in both clusters are a couple of important points. These clusters of oseltamivir resistant viruses were isolated from patients who have severe immuno-compromising conditions. These people were in immuno-compromised conditions either because of their underlying disease or because of treatment for their disease. Now, at this point, investigations are under way and WHO is in contact with the investigators but even while we wait for further details from the investigations, there are some points that we want to highlight. First is that to date most of the oseltamivir resistant viruses that have been identified in association with this pandemic, have come from sporadically occurring cases of disease. In this instance, we see two reports of clusters of oseltamivir resistance and this raises the question of whether we are seeing a change in the epidemiology of these viruses. The answer right now is that we don't know the full answer but it is more likely that we are not seeing a change, a major shift in the epidemiology or in the properties of these viruses with regard to oseltamivir resistance. So, right now we think that there probably is not a major change but this is why the investigations are going on in part. However, it does highlight that we do have particularly susceptible groups of patients out there, which again underscores the need for why surveillance is so important.

Now, in the second point that I wanted to make here is that most of the oseltamivir resistance that we have seen to date has arisen in association with the use of these drugs for prophylaxis but in this instance we have seen oseltamivir resistance develop in the face of treatment. Again it brings up the question, are these drugs being less effective in treatment. The answer here is that in fact to the contrary, most of the input that we are getting from clinicians around the world leads us to think that these antiviral drugs, when they are used appropriately and used early, are in fact reducing the number of serious outcomes and so they remain highly effective when used right. But, these clusters also point out that there are some unusual situations and people with severe immuno-compromising conditions are the most susceptible people out there. So, in the treatment of these patients we have to be ever mindful about how they are doing and how these drugs might be used. Now, one of the things that I do want to specifically address is that these are severely immuno-compromised people. There are people with milder forms of immuno-compromised states, for example, large numbers of people with HIV infection. Right now we do not see any evidence of a large impact in immuno-compromised people with milder forms and we do not see a large impact in HIV infected populations so again I want to stress that these clusters have been reported in people who have very severe immuno-compromised states.

The bottom line here is that treatment remains effective and in fact, there is growing evidence of their effectiveness but we do have to be vigilant in these very susceptible people.

Now the last point that I want to address before I throw it open to questions is that in the last several days we have also seen a lot of reports in the media about a mutation and this was specifically raised because it was Norway which recently reported seeing mutations in three patients who had severe disease. Since then there have been additional reports of the same mutation being seen in viruses in a number of other countries, such as Brazil, China, Japan, Ukraine and the US **[CORRECTION FOR ACCURACY: AND MEXICO]**. The question is whether this mutation again suggests that there is a fundamental change going on in viruses out there or whether there is a turn for the worse in terms of the severity. I think that the answer right now is that we are not sure. I want to answer why we are not sure in a way which explains why more investigations are needed. As you know these influenza viruses change frequently. Their gene properties change because these are viruses which frequently undergo mutations and so mutations in and of themselves are not necessarily important and in fact, if every mutation was reported out there, it would be like reporting changes in the weather - saying that there is a temperature difference of one degree one hour and then an hour later, saying there is a temperature increase or decrease of one degree. This kind of information does not really help anybody. But, what we try to do when we see reports of mutations is to identify whether these mutations are leading to any kind of changes in the clinical picture - do they cause more severe disease or less severe disease and also we try to look at whether these viruses are increasing out there, suggesting that there may be a change in the epidemiology. With this particular mutation we have seen that it is reported in people who have severe disease and we have also seen that it is also been reported in people who have milder disease. Right now one of the questions is, is it really associated with severe disease more often. The second point that though, is are these viruses becoming more common or are they relatively infrequent. So again, this requires looking at more viruses over time to get a sense of whether there is a change in the overall prevalence or number of these viruses. It is these kinds of investigations which require time and it is these kinds of questions which have to be answered before we can fully talk about the importance of one mutation or another mutation.

Le me stop there and throw it open to questions. Thank you.

**Kristen Kelleher:** Thank you for the opening remarks Dr Fukuda. Before we go to questions I want to remind everyone listening that an audio file of the broadcast will be available immediately after this briefing and a written transcript will be available later on the WHO website at www.who.int. Again, for journalists who want to ask questions, please type 01 on your keypad to get into the queue. Now for the first question, it is from Helen from CNN Medical News **[CORRECTION: MARION FALCO]** .

**Marian Falco:** I have two quick questions. Can you tell us about the ages of these immuno-compromised people who showed resistance to Tamiflu. Can you explain to me why WHO does not consider all children to be a high-risk group. Last week in the briefing it was mentioned that for countries who think that children are in a high-risk group. Here in the US all children and young people up to the age of 24 are considered high-risk. I am not clear why that is different with the WHO. Thank you.

**Dr Keiji Fukuda:** Thanks for these questions. In terms of the ages of the patients, I do not have that information. I think there are a lot of specific details about the investigations and the patients and the conditions that will be reported by the investigators but we don't have that information here. In terms of your second question why are all children not considered to be at high risk, when we talk about high risk what we mean are which groups of people are at highest risk for developing severe disease or complications and this is based on seeing what the effects of the infection are in different groups. So, based on the information that we see right now, it is clear that in children under five years, they are the ones who are hospitalized most often and then when you go up the age ladder, you see that the hospitalizations and complications occur less frequently and so, depending on the information that you have, different groups might make different cut-offs in terms of the age of risk but I thing that it is clear that the very youngest children are at higher risk for being hospitalized with severe complications and that the risk for those events decrease as we get older. Thank you.

**Kristen Kelleher**: Thank you Marion. The next question is from Helen Branswell of the Canadian Press.

**Helen Branswell**: Thanks very much. Keiji. In your opening remarks you said that you think that it is going to turn out to be unlikely that the clusters of resistant cases are a signal of the changes in the epidemiology of the virus. Can you explain why you think that is and also I was hoping you could address a situation that has arisen in the United States - I don't know if you have seen it yet but there is a report of a paediatrician from West Virginia who tested positive for the virus twice - she got sick in August and again in October**.** Her tests were confirmed by CDC. Is it thought that this is really a sort of an outlier, you know a one in a million type of thing or is anybody looking at the possibility that immunity to this virus might be so short lived that people could get sick multiple times in a short period of time.

**Dr Keiji Fukuda**: OK thanks Helen. Again, let me address the first question first. In this particular instance we are looking at clusters of oseltamivir resistant viruses take place in fairly specialized settings so these are hospitals taking care of very immuno-compromised patients and if these viruses in this situation do not spread into the community spread out more widely again what is point out is that there needs to be a lot of vigilance taken with those groups of patients but probably does not have a big implications for the overall patterns of illness in the general community. However again like all new observations it is something we have to keep on top and watch out and make sure we don't see this is a spreading phenomenon. Now in terms of your second question, I have not seen specific reports I have seen mentioned of this person who has infected twice. In general with influenza infections most people who become infected with influenza remain immune to infections for an average at least for couple of years and so it is unlikely that with the pandemic virus we are dealing with the completely new phenomenon in terms of protection. So again, I think that there are always some exceptions to rules but it is unlikely this is a very broad phenomenon. So I will be surprised if we hear about many cases such is this. Thank you.

**Kristen Kellehe**r: The next question is from Vera Custis. Vera? [CALL DROPPED]

Let me take this moment to again remind journalists who want to ask questions to please type 01 on your keypad to get into the queue. We have another call on the line; it is Fergus Walsh, BBC.

**Fergus Walsh, BBC:** Thank you very much indeed. Here is my question. I am in a couple days ago the Health Protection Agency in England estimated that up to a third of school children may have had swine flu and also estimated that only about half of them would have had any symptoms at all so half of them were asymptomatic and I wonder whether any kind of work had been done internationally to give a sense of how much of the world's population has now had contact with this virus.

**Dr Keiji Fukuda**: I think that when we look at past pandemics you know we actually this question came up a number of times at the start of the pandemic and we look at past pandemics we have said that based on those that we can anticipate that over the coming year that we might expect a third or perhaps the more population to become infected by the new pandemic virus and so I think the estimates from the UK you know are in keeping with those kind of rates we have seen in the past. Again there are studies which are going on to look at the levels of antibodies in different communities and this will provide the most definitive information that we have but I think that we still need to see those kind of studies done at the end of the pandemic to know about what percentage of children of different age of groups getting infected. Thank you.

**Kristen Kelleher:** The next question is from Eliane Engeler from Associated Press.

**Eliane Engeler:** Yes. Hi. Just a question about the numbers of oseltamivir-resistant viruses you mentioned in your introduction, that there were 75 viruses and I understand that means 75 patients, and then you mentioned 4 patients in the US and I think 9 in the UK, so where are the others, and is it really viruses equal the persons? And secondly I am not quite clear about the report mutated cases of flu in China. Were the same mutations as were seen in Norway and in Brazil and other countries? Thank you.

**Dr Keiji Fukuda**: Let me take these 3 questions. But let me first clarify in the UK there were 9 patients who became ill with pandemic influenza. From those 9 patients, 5 of them have oseltamivir-resistant viruses, 3 of those patients the testing results are going on. In 1 of those patients 1 virus was found to be sensitive. So anyway 5 viruses from that cluster. The other viruses do come from different individuals that have been reported from the start of the pandemic. So in general these other viruses come from people who have developed resistant viruses again in many instances they have developed resistant viruses because they were taking prophylactic doses of oseltamivir and not treatment doses of oseltamivir. So anyway these have been viruses which have been seen since the early part of the summer when the pandemic first started. And in terms of your question, yes the mutation that I am talking about in the countries that I mentioned, and you asked about China specifically, but also the other countries you are talking about, the same mutation that was seen and reported in Norway. Thank you.

**Kristen Kelleher:** Next is Mr. Mitamura from NHK.

**Mr. Mitamura:** Thank you for talking my phone. I would like to ask again about the cases of vaccines side effect in Canada and so the rate of side effect in Canadian cases are not unusual compare with these seasonal vaccines cases. Is that correct? One more things I would like to ask is that the mutation virus, when did WHO had found the first case of this mutation? Thank you.

**Dr Keiji Fukuda**: OK. In terms of the rates of anaphylaxis. Yes the rates reported by Canada overall have been quite low and so that is the reason why the report of the 6 cases from one lot of vaccine stood out and so than they identified by that number. And again in general the rates of anaphylaxis reported for vaccination overall in Canada have been very low. In terms of the mutation, now this is a mutation which historically had been identified as I believe, many years earlier, this is a mutation at the position called 222 in the [….] gene. I do not know exactly when the very first mutation was identified in this current pandemic virus but we know that from the cases identified in Norway the first identification of this mutation in Norway was earlier in the summer. So sometime around June or July with the second mutation being identified later in the summer. So otherwise right now I don't know when the mutation was first identified worldwide among the pandemic viruses. We would have to get back to you on that. Thank you.

**Kristen Kelleher:** The next question is from David Brown at *The Washington Post*.

**David Brown:** Hi. Thanks a lot. Dr Fukuda, as I am sure you know, there's been some reports that the epidemic is peaking in regions of the United States and starting to fall off. I am wondering is there is any good explanation for why it doesn't just run through the population, all of the susceptibles, and then decline, but why it would peak, you know really in optimal flu season, and then presumably come back in a couple of months.

**Dr Keiji Fukuda**: Good question David. That is a difficult question, but one of the general observations about all infectious diseases like influenza is that when you have outbreaks they generally peak and then begin to decline before everybody who is susceptible in that population gets infected. And I think that if we think about, you know, these populations of people, you know people have contact with other people, and so if a person who is not protected runs into somebody who is infectious they get infected. But if after a while you have enough people infected, and then they become protected, you will see that chances for running into people who are susceptible begins to go down, and that's when you begin to see the decrease in infections going on in a population, and eventually it goes down low enough so that you still can have susceptible people out there who could potentially become infected, but in that current epidemic or that current episode do not become infected, and then later on as time passes again the conditions change for whatever reasons, and then it is possible for the virus to get reintroduced. Overtime with influenza we see that it occurs partly because the virus itself changes, which means that it begins to escape the immunity which is built up, but I suspected it also has to do the fact that people are not static, and populations are always mixing, and so the mix of protected people and susceptible people also changes. It is quite a complex phenomenon that we see over and over again with these influenza epidemics.

**Kristen Kelleher:** We have time for just a few more calls. The next call is from John Zaracostas, BMJ Geneva.

**John Zaracostas:** Good afternoon Dr Fukuda. Was wondering if you could elaborate, sir, if the immuno-resistant cases were suffering from cancer, tuberculosis or advanced cases of AIDS. Also with reference to anaphylactic shock in Canada. Is the substance that triggered the allergies benn identified yet? Thank you.

**Dr Keiji Fukuda**: So John. I don't know all of the conditions that led to the patients being immuno-compromised. I understand that many of them had malignancies, more specifically hematologic malignancies. So these patients were also under treatment which again can further compromise your immune system. But again I don't have a further breakdown of what specific conditions led to their immuno-compromised states.

In terms of the specific substance or why people developed anaphylaxis, I think this is a very important point. I think when we hear about cases of anaphylaxis then the immediate temptation is to jump and think about the vaccines. Is something wrong with the vaccines? In fact, this lot of the vaccines was about a 172 000 doses of vaccines and much of that vaccine was administered to many people, most of whom developed no reactions at all. And so the number of people who developed anaphylactic reactions who are really quite small and so I think it points out there is some combination of factors involving both the persons and then what they are exposed to the pandemic vaccines. So it may be that in fact this pandemic vaccine is exactly the same as every other lot of pandemic vaccine out there but it happened to be given this group of people who for whatever reason were more prone to developing anaphylaxis. So I think these are again complicated issues to be teased out. This is why these kind of investigations are done. Thank you.

**Kristen Kelleher:** Our last question today will be from Gabriella Sotomayor from Notimex, Geneva.

**Gabriella Sotomayor**: Thank you very much Dr Fukuda. There are some reports of H1N1 linked into a rise in bacterial pneumonia cases. If you could comment on that and, secondly you mentioned several countries with the mutation cases but I am not sure if you mentioned Mexico, if you could clarify that. Thank you very much.

**Dr Keiji Fukuda**: Thank you Gabrielle. Let me address the second question first. I don't know of any reports of this mutation being reported in Mexico. So it may be that we hear of such reports later on but right now I don't know of any such reports. **[CORRECTION: VIRUS MUTATION HAS BEEN OBSERVED IN MEXICO. SEE EARLIER PANDEMIC INFLUENZA BRIEFING NOTE 17 OF 20 NOVEMBER AT http://www.who.int/csr/disease/swineflu/notes/briefing_20091120/en/index.html]**

In terms of your first question, one of the ways that influenza typically makes people sick is that you have an influenza infection and then after that influenza infection occurs, it is followed by a secondary bacterial infection and in fact, this is the way that seasonal influenza often makes people sick and leads to pneumonia. One of the surprising things about the pandemic influenza virus is that many of the serious cases and many of the fatalities that we saw, were a result of the virus directly attacking the lungs and causing a very serious illness. However, it is true that we have now seen more reports in which people do not necessarily have serious disease directly from the virus itself alone but that people have developed secondary infection, such as staphylococcal infections or streptococcal infections which are common bacterial infections that can follow influenza. So, we see this more often, we see this reported more often. Again I think this is not a surprise, this is what we often see with influenza. I think the bigger surprise was that we did not see more of these reports earlier in the pandemic. Thank you.

**Kristen Kelleher**: Dr Fukuda, thank you very much. That will conclude the briefing today. To remind you, an audio file of this briefing will be posted immediately after the briefing on the WHO web site at www.who.int . And a written transcript will be posted on the web site later. So thank you all for listening. And thank you to Dr Fukuda.

# Transcript of virtual press conference with Dr Keiji Fukuda, Special Adviser to the Director-General on Pandemic Influenza, World Health Organization

3 December 2009

**Nyka Alexander, WHO communications office:** Good afternoon. We welcome you to WHO's weekly virtual press conference, today on December 3rd, 2009. My name is Nyka Alexander. With us is Dr Keiji Fukuda, Special Adviser to the Director-General on Pandemic Influenza. Dr. Fukuda is joining us remotely from London today. He will be giving a situation update and then we will take your questions. Dr. Fukuda, if you are ready, over to you and thank you.

**Dr Keiji Fukuda:** Thank you Nyka. Hello everybody and again welcome to the weekly virtual press conference and apologies for not having this on camera but as Nyka mentioned I am offsite. Let me get started and I will follow the usual format by pointing out a couple of main things as well as providing an overview of the current situation. At the current period after going into this pandemic for about 8 months, it is clear that it continues to evolve and pose new challenges and raise new concerns and that we continue to face ongoing uncertainties about the pandemic.

In the face of this, WHO strongly emphasizes that continued global cooperation is really the essential basis for fighting this pandemic. And not just this pandemic but also future global public health challenges. I will come back to this point and I will give you some good examples.

In terms of where we are in the disease activity, we continue to see that most activity is in the northern hemisphere with lower levels in the southern hemisphere. In the northern hemisphere we continue to see an up and down pattern by countries. So what you see in one country is not necessarily what you are seeing in another country.

Till this point, overall, it's too early to say whether activity is peaking in the northern hemisphere and at this point it is also not possible to predict what we are going to be seeing in the spring time.

In terms of vaccination, we estimate that over 150 million doses of vaccine have now been distributed in about 40 or more countries. And again, similar to last week, so far we have not seen any unexpected safety issues emerge, and the safety profile continues to be similar to what we see in seasonal vaccines.

When I started the virtual press conference, I was emphasizing global cooperation and what I would like to is use vaccine as an example to explain what this really means. What I would first like to do, is review how we got here and to make it a little bit easier to understand all the issues.

If you first go back to April, this is when the pandemic cases were first identified, and at that time of the year it was very unclear what the future severity of this pandemic would be. Nonetheless, at that time, what WHO did was immediately start initiating all possible steps to protect people. We did that based on a couple of different things, but mainly because from historical knowledge we knew how past pandemics had, really caused a great deal of disease and death world wide. We also knew and wanted to take advantage of the fact, that a large number of countries had been preparing for the next pandemic and to build on these foundations.

Several steps were taken immediately by WHO, and this included measures such as increasing levels of monitoring and surveillance around the world, raising awareness and communications around the world, and then providing professional, community and personal level guidance on protective actions that people could take. Development of these actions each involved working with a range of global partners, and this is a general principle that we follow at WHO: to be as inclusive as possible. One of the specific actions taken by WHO was to focus on vaccines. Again, there were two basic reasons, why we focused on vaccines from the very start of the pandemic. The first and most basic one is that when you are dealing with infectious diseases, it is simply true that people with some degree of immunity usually do much better than those people who do not have any immunity. People can develop immunity to infectious diseases in a couple of different ways. One of them is simply to go through actual infection, but the cost  in terms of disease and death can be very high for people. So for example, if we take polio as an example, you can get people immunized to polio by letting them get infected, but this can have a very terrible price. So the alternative approach is vaccination. It is clear when you look at the Twentieth Century that vaccines have been one of the most effective and most cost-effective and safest ways to protect people against a wide range of infectious diseases. Again, these include diseases such as yellow fever, polio, measles, meningitis, small pox, and so on. There a list which goes on and on, but the idea is basically the same. It was true and is also true for pandemic influenza.

The bottom line is that when you are facing a new infectious disease, really many infectious diseases, protecting people through vaccination is a much preferable option than simply sitting back and taking a chance on infection. Now, it's clear that in this pandemic, not all people are at equal risk for severe outcomes. In this pandemic, we have seen that the deaths are concentrated in younger people and it's been concentrated in certain groups like pregnant women. They have also seen that vaccines offer a really safe and effective way to protect such people.

Now the second main reason why WHO moved very quickly on vaccines, was that based on decades of experience, it was clear that making and distributing and administering the pandemic flu vaccine was going to be a very complex, difficult and time consuming task. So from the outset it was clear that we would have to be working with multiple partners, both in the public and private sectors, and working under very tight time restrictions if we are going to be able to make and get out pandemic vaccines. Given these considerations, we did move quickly to mobilize these global partners. And so some of these partners include groups such as ministries of health, public health agencies in several different countries, physicians from around the world, and these kinds of groups and people provided WHO with critical information on who the disease was impacting, what the impact was.

We worked with over a 120 national laboratories in countries, as well as several different national regulatory agencies, both to take a look at the viruses, monitor how they were doing, and also to select candidate viruses that could be used in a vaccine. And finally we worked with the private sector, that is, vaccine manufactures. In this process, maintaining and engaging the private manufacturing sector has been a very critical step, again, because this group has the unique and essential role in the vaccine manufacturing process.

In the first place it's the private sector which makes vaccines. Most vaccines which is available in the world for all diseases are not made by the governments or by the public sectors but it's made by companies in the private sector and these companies are located both in the developed countries but also in a number of developing countries.

Also, this group that has really a unique expertise and knowledge of vaccines because of their manufacturing of the vaccines, it's essential for public health really to act as this kind of knowledge and know-how, if we are going to fully utilize and understand the products in the best possible way.

It is also clear, however, that simply making vaccines is not the end of the story, the vaccines has to be gotten out of countries, it has to be administered to people and you have to face questions, such as who do you give the vaccine to, and for what reasons. And to answer questions like this, WHO has also reached out and engaged a number of people, through groups such as advisory groups, there is one called SAGE, Strategic, Advisory Group of Experts which provides guidance to WHO on immunization issues, and we use this group to obtain additional scientific and public health guidance and how to use the vaccine. Now the members of SAGE come from around the world, they represent various public health and scientific disciplines, but what it is is another good example of how WHO fully uses global partnerships and tries to be as inclusive as possible, to get the best possible input to make the decisions needed to move ahead when addressing something like pandemic influenza.

In summary on this main point, what I want to point out again, is that WHO has worked very closely and will continue to work closely, with all key partners, both in the public sector and in the private sector to get the input which is needed really to develop the best pubic health actions. We actively embrace the idea, that working with a broad coalition of partners, in this instance really a global coalition of partners, is essential for handling these kinds of threats. Now this approach is definitely necessary for the current pandemic, but I think it's also clear that it's going to be necessary for the future global health threats as you can appreciate I think, that we have been a very highly interconnected and fast-moving, globalized world now, and WHO considers that working in isolation is really not an option. We really need to fully utilize all capacities around the world to address these kinds of issues. Let me stop here, I think I will just open it for questions at this point. Nyka, back over to you.

**Nyka Alexander**: Thank you Dr Fukuda. Before we go over to questions, may I remind everyone that as usual an audio file of Dr Fukuda's briefing will be available immediately afterwards, on the WHO web site, www.who.int and a transcript will be available later today or perhaps tomorrow morning. To ask a question, please type 01 on your keypad. The first question is from Helen Branswell, Canadian Press, Helen please go ahead.

**HELEN BRANSWELL, CANADIAN PRESS:** Hi, thanks very much for taking my question. I'll try to squeeze in two if I could please. I heard you when you said that it is too soon to know what's going to happen in the spring but I am wondering if WHO has given any thought to when it would feel safe to declare the pandemic over. What is the mechanism for doing that, and how would you do that, and I ask, because there are certainly people who feel that this has turned out to be much less of a threat to global health than was first thought. In fact CDC has come up with this fatality ratio of 0.018, which people are pointing to suggest this is quite a mild event, and I am wondering if you could address both that notion that it's very mild, and when you feel it would be safe to declare it over?

**Dr Keiji Fukuda**: Sure, good questions First let me start with the second question and I will come back to the first question. In terms of the impact of the pandemic, of the important point is that, from the very beginning of the pandemic, we had pointed out repeatedly that we don't really know what the future is going to bring. And we have also noted that when we look at the Twentieth Century the experience has been that pandemics can range from relatively mild side, to being on the more extreme side. I think at this point, it is fair to say that we still haven't fully gone through the pandemic, and that it is possible that there could unexpected events which occur as we continue to go through.

But I think the other point is simply true that it is quite possible to have a pandemic on the milder side and if we are experiencing that, and if the number of serious cases is kept down, and this is something, again, something for which we should all be thankful.

Now in terms of how we move from a pandemic period to a non-pandemic period. Again if we look back the history for some guidance, we will see that we typically have a period in which pandemic infections are quite high. Then we go a transition period in which those newly emerged viruses, pandemic viruses, often become seasonal influenza viruses.

So to go through this, what WHOis doing is reaching out to get the best possible technical and scientific assessments of where we are. And then I think that we will also necessarily engage some of the other deliberative bodies, such as the International Health Regulations, to make some of the formal decisions needed to step away from the pandemic period and go back down to a non-pandemic period.

And then also, I think that there will be a number of questions of practical importance, related to vaccines and so on, and for some of those issues that we all could be reaching out to some of the other advisory boards that we often use such as SAGE.

**Nyka Alexander**: Our next question is from Jason Gale, from Bloomberg.

**JASON GALE, BLOOMBERG**: Hi Keiji, I would like you to talk about clinical attack rates. The November 13th WER talked about estimates of 7% to 15%. Data from sero surveys are being compiled in some countries. What is your best estimate now, of the clinical attack rate, and how does the infectiousness of the pandemic virus compare with seasonal flu?

**Dr Keiji Fukuda**: To provide from context, attack rates for influenza, often vary by age. And they often vary by where you are having people aggregated. So for example, typically, with influenza we see that the attack rates are highest in children. And they can be higher in groups of children when they are located in schools or located in different places where they assemble. And frequently the attack rates are lower in older people, and frequently in people who have less contact with other people. So I think that the estimates you quoted of about 7 - 15%, in general, may be reasonable. I think that there are also estimates of attack rates of about 30% in children and this would also be in keeping in what we typically see.

Now these attack rates are going to be a little different than what the seroprevalence studies show us. The seroprevalence studies will eventually probably show that in some groups the infection rates are going to be higher recognizing that some people develop illness which does not meet the symptoms and is very mild. But I think that the kinds of figures which have been quoted are probably reasonable. Thank you.

**Nyka Alexander**. Thank you. Before we go the next question, just to remind every one that if you have a question to ask in the queu, type 01 on your keypad. Next up is Fergus Walsh from BBC. Please go ahead.

**FERGUS WALSH, BBC**: Thank you very much for taking my question. Two quick questions. Firstly, when do you think the H1N1 Pandemic strain will become part of the seasonal flu vaccine, and which components of the trivalent vaccines might it replace? And secondly, on pandemic strain drift, do you have any parameters on how virulent or indeed more mild the H1N1 pandemic virus could become, are there limits to how severe it could become if it did mutate?

**Dr Keiji Fukuda**: OK. Again, two good questions. Let me take the first question and then I will go to the second.

In terms of the vaccines, there are a couple of different processes in groups which make substantive input into the process. There will first be the selection of what viruses should go into influenza vaccine, and this is done by a group of WHO Collaborating Centers who also work with a number of regulatory agencies. Both go through all the global data and to look at the trends and patterns among influenza viruses and then decide which viruses should be recommended for influenza vaccine.

And then normally, what goes in the vaccine itself is then decided by national regulatory authorities. So the national regulatory authorities for countries in which vaccine is manufactured will go ahead and make the recommendations for what should go in the vaccine for that country. And so they could recommend making a monovalent vaccine or a trivalent vaccine and so on.

In the pandemic situation, we also asked for SAGE to provide some overall guidance and advice on this issue, because it is an unusual period. But I expect that these are the groups that will be involved in making these decisions. I think it is not possible to second guess what the decisions will be, but they are the groups that will be involved.

Then in terms of drift. Drift is a process in which the virus mutates. And based on those mutations, the properties of the virus can change. So when we look at influenza, we see that there are examples where viruses become less virulent and less dangerous for people. For example when we look at the 1918 situation, we have seen that virus when it first came out was very lethal for people but over time became milder. But we have also seen that there are examples of viruses coming out which are relatively mild at the beginning and then over time become more pathogenic for people.

So again, there are examples of viruses going both ways. Because we fundamentally do not know and cannot guess how these viruses are going to change. I think it is not possible to second-guess what direction drift will take us. Although we fully expect that the drift will occur over time with these viruses as they do with all flu viruses. Thank you.

**Nyka Alexander**: Just before we go to the next question, I want to bring our media colleagues, 2 documents that we have on our website. One is on osetalmivir resistance in severely immuno-compromised patients. It is the WHO investigations into two clusters of these. And there is another one - WHO use of advisory bodies in responding to the pandemic. Both of these are available on http://www.who.int where one can generally see all our pandemic information.

The next question is from Joseph Masselmane, Sun Media, Kuala Lumpur. Please go ahead.

**JOSEPH**: Dr Keiji, I would like to ask you, could you please confirm that the virus has become resistant to Tamiflu antiviral as reported in the WHO website yesterday. And cases reported in the UK and US, has already reports of a mutated strains in Japan, China, and Norway. How seriously can these mutations impact global public health? With one out of the two antivirals available currently, already facing resistance, and how profound is the disparity in terms of the drift variance in these mutations? Thank you.

**Dr Keiji Fukuda**. OK. Let me try to address these. It is very important point for everybody to understand clearly. Right now, WHO has been informed about 96 H1N1 Pandemic viruses which are resistant to oseltamivir. There are a huge number of influenza viruses, pandemic viruses, which are out there, and many of these viruses have been studied in laboratories, so it is only a small number of influenza viruses which have been identified as resistant to oseltamivir. So right now, it is important to emphasize that we do not see widespread resistance to oseltamivir anywhere.

However, as was mentioned, we have heard that there are oseltamivir resistance in a number of countries, in small numbers. And then again most recently, as we discussed last week, that have been some clusters of oseltamivir resistance occurring in people who are severely immuno-compromised. So right now, we still do not have anything to suggest that there is widespread resistance. Most viruses remain sensitive to oseltamivir. However, we are always concerned about the emergence of resistance among any kind of pathogens, especially pandemic influenza. It is something that we will be monitoring closely, and we will be monitoring whether there are any significant changes in the spread of these viruses. But we do not see it right now. Thank you.

**Nyka Alexander**: Our last question is from Richard Knox, NPR. Richard please go ahead.

**RICHARD KNOX, NPR**: Yes thank you very much, and hello Dr Fukuda. I want to follow up on points that Helen raised earlier. She mentioned that WHO, I mean CDC, has been calculating a case fatality rate of [0.018] percent which is about a 100 times less severe than the 1918 case fatality rate. Does WHO have its own case fatality rate or a range, and secondly, again following up on Helen's questions, can you indicate when WHO will convene consultations on transition to a post-pandemic period and what will trigger that?

**Dr Keiji Fukuda**: Richard, let me take the first question. No, WHO has not calculated case fatality rates based on current information. But there is a reason for that and it is an important reason to understand.

With the current pandemic, we really have data which is almost an anomaly, when we look at how influenza has been counted in the past. So when we look at the 1918 pandemic for example, the way that we estimated the number of people dying from that pandemic, was really to look at vital registry data available in the US but also in other countries. And then to use various modelling techniques to estimate how many of those deaths were related to the pandemic and not to other causes.

And this is typically the approach which is used up until the present for seasonal influenza. People do not typically count influenza deaths on a one-by-one basis. And so we do not have a lot of data on laboratory confirmed deaths for seasonal influenza. But in this current period, with the pandemic, that is the data that we have, and the reason why we have it is that there is so much interest in it. But also it is much too soon to be able to have the vital registry in death data that is typically used to model and estimate overall deaths. And so I think that it will take another one to two years, after the pandemic, for those data to be collected and for the kinds of estimates which are typically done for seasonal influenza, but also for pandemic influenza, to be done to make the estimates.

I think, that when we have those estimates, then we will be in a much better position to really talk about how does this pandemic stack up with the earlier pandemics, as well as with seasonal influenza.

So in terms of the second issue, there is no set date right now for when the transtition discussions on transition will take place on more formal settings, but from the beginning of the pandemic, again, how procedures are done, what steps, what considerations, should be taken both for going up in terms of the phases, but also going down  in terms of phases, has been under discussion and under consideration. So I anticipate that at least in some time in 2010 we will be discussing this in more formal settings, more concentrated ways, to try to get the best scientific picture, of where we are in this pandemic, whether we should expect a third wave in countries to come, or not, whether we think that there is convincing information to say that we are really moving away from the pandemic period. Again, it's a little bit early to begin those discussions now, because we are still in a period where some countries in the northern hemisphere are still increasing in terms of their infections, even though in some countries  as such as the United States and Canada it looks like infections and these cases are going down. That's still not true for the entire northern hemisphere, but it will have to wait a little bit longer, Thank you.

**Nyka Alexander** Thank you Dr Fukuda, and thank you to all the journalists online. This has been the virtual press briefing from WHO Headquarters today with Dr Keiji Fukuda, Special Adviser to the Director-General on Pandemic Influenza. I would like to remind you that there will be an audio file posted on our website shortly, and later today or tomorrow morning a transcript of the briefing. The web site is www.who.int. The next virtual press briefing should be next Thursday. Thank you again, and have a good day.

World Health Organization

# Transcript of virtual press conference with Dr Keiji Fukuda, Special Adviser to the Director-General on Pandemic Influenza, World Health Organization

## 17 December 2009

**Nyka Alexander:** Good afternoon. We welcome you to WHO's weekly virtual press briefing from WHO today on December 17th, 2009. My name is Nyka Alexander and with us is Dr Keiji Fukuda, Special Adviser to the Director-General on Pandemic Influenza. He will begin by giving a situation update, and will then take your questions. Dr Fukuda, over to you now.

**Dr Fukuda:** Thank you Nyka. Welcome everybody, as the year draws to a close, we want to welcome you to this virtual press conference. As usual what I will do is try to highlight a couple of main points and then will throw it open to questions. Now one of the first points reflecting questions coming to WHO is that it really probably remains too early to call the pandemic over. I will go into a little bit more detail about this. But the second point that I also want to make, and an important one, is that given the current situation, WHO continues to provide all possible support to especially vulnerable countries in dealing with the current pandemic situation. Now let me bring our attention back to the pandemic, and where we see things right now. Now we are now about 8 months into the pandemic and one of the common questions coming to us is, that is the pandemic over, is it time to call it, and really the answer is, that it is still too early to make such a call. And there are couple of main reasons for this. In the first place, again I want to point out that the pandemic is a global event, it is really the worldwide spread of the virus and it is not a simply a regional event in which we see some activity going on in some parts of the world. Because of this WHO continues to monitor this situation, in all parts of the world, both in the northern hemisphere and the southern hemisphere. Based on this we see that activity or infections continue at quite high levels, in several different counties. For example, we see that activity continues to be at high levels in parts of Europe such as France and Switzerland, in the Czech Republic. We see that activity continues to be high in parts of central Asia such as Kazakhstan and Kyrgyzstan and we also see that activity continues to be high in some very large countries such as Russia. These were examples of countries around the world in which we continues to see high levels of activity. Now the second reason is that it is clear in some parts of the world, such as North America and in some parts of Europe, we have seen that the pandemic activity for now, has clearly peaked and is on the way down. But one of the points about this is that the peaking has occurred extraordinarily early for influenza and we still have several months for winter to go and one of the big questions which is still before us is whether we expect to see yet another wave of activity occur or perhaps at late winter or in the early spring months and the answer right now is that we simply are not able to answer this questions right now. We are continuing to assess and monitor activities but right now we cannot predict whether we will see another upsurge and significant activity in the earlier parts of 2010. Based on this assessment, based on the fact that we continue to see high levels of activity in many countries and we remain uncertain about what we might see in the earlier parts of 2010, WHO is very much continuing to provide support to countries which are particularly vulnerable in the face of pandemic infection. Now from the onset of the pandemic, this has really been the primary focus of WHO's efforts, which is to provide support to the countries, to be able to be ready to respond to the spread of this infection, and disease. As part of this effort, just one part of it, one of the things that we have given particular attention to, is vaccines. Early on as the pandemic developed, WHO began identifying those countries that would have little of no access to vaccines. As you remember, both the Secretary General of the UN and the Director General of the WHO made appeals to both to the manufacturers, and also to the countries to help provide vaccines and support to those countries, that have little access no access to pandemic influenza vaccines. In response to this request in the situation, 6 manufacturers and 12 countries so far have pledged approximately 180 million doses of vaccines to be distributed to approximately 95 countries. There are other countries who are negotiating with WHO about donations, but right now we can say that there are 6 manufacturers and 12 countries which have made pledges. Now one of the important things about the vaccines which are being donated to WHO is that they are both adjuvanted and non adjuvanted vaccines, and there are negotiations about live attenuated vaccines. But before any of the vaccines are sent out to the countries, they will all be prequalified by WHO, that is we will go over and we will make sure, that they are manufactured according to standards, and that they pass regulatory procedures, so that they are safe and effective for the countries that they are given to. Now one of the things that we are doing is moving as quickly as possible, with these many partners to make vaccines available to the countries. Now to receive the donated vaccines, we are asking the recipient countries to do three things: the first is simply to make a formal request to WHO so that we know that the country would like to have the vaccines; the second is to work with WHO to agree to some term and conditions, so we are both clear about how the vaccines will be provided, how they will be handled and so on; and the third step is for the recipient country to develop, the national plan, with WHO, to make sure that the vaccine once its provided, and is received in the country, is handled properly, so that it goes to the right people. So three basic steps for the vaccines. Now because this is an unusual process this is very large and complicated operation and not one that anybody engages in a regular basis, WHO has provided as much help as possible to these recipient countries. So for example we have held 9 workshops in all regions of the world and these workshops are designed to help provide support on developing plans to answer questions and so on. So a lot of this work is going on in the past few months. So at this point we hope to begin deploying the vaccine in the next few weeks. And to get it to the first countries, a lot of this work in the distribution of the vaccines will be done with partners, one of the key partners is the United Nations Operations Group known as UNOPS. They are the group that we are working with to help actually get the vaccines physically to the different countries. So again I want to point out that at this time, we believe that it is too early to say that the pandemic is over. We are monitoring the situation carefully but at this point it is premature and that again, because of this, WHO is continuing to work very hard in terms of providing as much support to countries as possible. So let me end there with the opening part of this virtual press conference and let's throw it open to questions. Thank you.

**Nyka Alexander:** Thank you Dr Fukuda. Before we go over to questions, may I remind you that an audio file of Dr Fukuda's briefing will be available immediately afterwards, on the WHO web site and a transcript will be available later today or tomorrow morning. To ask a question, please type 01 on your keypad to get in the queue.

The first question is from Martin Ensuring, Science Magazine. Martin, please go ahead.

**Martin Ensuring:** Yes, hello, and thank you very much. Did you just say that no vaccine has been shipped to any countries yet, because I though that the plan was to have it ready late November or to send it out late November, early December, so what happened, what went wrong. And also, isn't it just too late now that as you say that the pandemic seems to be on the vain in so many countries.

**Dr Fukuda:** Martin, thanks for those questions, in terms of the first question we are hoping to get the vaccines out as early as possible. That has always been the main goal, and we are hoping to get the vaccines out in November or December. This process, this operations has been extremely complex, as opposed to some other large vaccination efforts, for example, polio in which we are trying to eradicate the virus or measles campaigns. In those instances we have many people out there who are really set up many structures that are set up, to handle the vaccines and to administer the vaccinations on large scale. In terms of this pandemic vaccine operations, really this has been a new operations evolving a large number of companies and I think that the logistical issues and the regulatory issues combined have been extremely complicated and then also to get the countries ready to handle vaccines and to administer them to groups of people that they often normally do not focus on for vaccination efforts, has really been a very complicated task and so I think that we are still hoping to get the vaccines out soon. The first doses have not gone out yet, but we are I think very close to that. In terms of the second question is it too late, I think the answer is simply no. There are a couple of reasons for this: the pandemic virus is now a virus which has really spread around the world, and it is quite likely this is an infection that we continue to see circulating for a number of years. We also, as I mentioned, do not know what we are going to see in the springtime. So for these reasons, and for the high likelihood that many people are going to run into this virus in the future, I think that it remains quite prudent to push ahead with the vaccination efforts. Thanks you.

**Nyka Alexander:** May I remind journalists, that to get in queue, type 01 on your keypad. Next question is Kate from Reuters. Kate, please go ahead.

**Kate:** Hello, I would lie to ask you weather you could comment please on report that some countries are in negotiation with some drug companies to return some of their unwanted supplies of H1N1 vaccines.

**Dr Fukuda:** Kate, I don't have any first hand knowledge of any of the negotiations going on between the countries and vaccine manufacturers, and so, that's simply something I don't have any information on. I think that question would have to get directed either to the countries or to the manufacturers. Thank you.

**Nyka Alexander**: Next question is from John Zaracostas from BMJ, please go ahead.

**John Zaracostas:** Good afternoon Dr Fukuda. I was wondering the target few months ago was to get 300 million doses donated to capture about 10% of the core population in the poorer nations. What you just mentioned is 180 million is that still short of your target. Am I correct?

**Dr Fukuda:** John, partly correct, but partly not correct. The target for getting vaccines out is about 2% to 10% in different populations, and if we go with the 10% figure, that would be approximately 200 million doses for the 95 countries that have limited access. That 10% would cover both the healthcare workers and first responders in countries plus allow the countries to vaccinate some of the groups of people at higher risk for infections. So the target has been 2000 million doses, the 180 million doses is close to that and we will see whether further negotiations increase that amount to the 200 million. Thank You.

**Nyka Alexander**: Next question is from Jane, from AP in London. Jane, please go ahead.

**Maria Cheng:** I think it's me, its Maria Cheng in London. Thanks for taking my call. I had a couple of questions about the countries that are aligned to get the donated vaccines. I wondered if you could clarify which countries are getting it in the next few weeks, which ones are in line to get it, if there're any priorities to be place on countries that have a large population of immuno suppressed people. And also I wanted to know if you had any idea of what the lag would be between the time the vaccine gets delivered and when it actually gets to be put into people's arms. Thanks.

**Dr Fukuda:** Thanks Maria. The first 3 countries that we are hoping to get vaccine out are Azerbaijan, Afghanistan and Mongolia. But there is a group of 35 countries whom we are planning to get out vaccine first followed by the rest of countries. So there is a sequence of deployment for the vaccines and again the vaccination effort will be to get vaccine out for approximately 2 per cent of the population of the recipient countries in order to allow health care workers to be vaccinated. The premise for this is that health systems and hospitals are where people with all sorts of illnesses end up and so to protect the ability of hospitals to function is one of the primary goals for the first mono-vaccine which is to go out. That would be followed later on by providing enough vaccine for eight per cent of the population , so a total of 10 per cent of the population of these countries. Now, the way these countries were selected reflects the fact that we are seeing more activity going on right now in the northern hemisphere as well with less activity going on in the southern hemisphere but again recognising that there are countries both in the north and in the south that do not have access to these vaccines. So, this is the overall rational for getting the vaccine out and to try to get it out in a relatively sequenced way. Now, in terms of the amount of time from when it arrives in a country to when it actually gets to people, I think that this will be variable from country to country but we are hoping that the time lag between the receipt of the vaccine and the administration into people is minimal and in the order of a few weeks or so. Thank you.

**Nyka Alexander:** Our next question is from Mr Arai from Kyodo News in Geneva. Please go ahead sir.

**Mr Arai:** Good afternoon Dr Fukuda. Thank you for taking my question. I think you confirmed that the death toll of the H1N1 2009 is over 10,000. My question is what is the assessment of this number? I think some people are questioning that it will be much fewer than the seasonal influenza so what is your view of the fatality rate?

**Dr Fukuda:** My view is that right now we have over 10,000 deaths in which the deaths are associated by laboratory testing with the new pandemic virus. Now this is likely to be a quite an underestimate of the actual number of deaths which have occurred out there. Sothe reason why this has been confusing is that with the current pandemic situation, the numbers of people that have been reported to die from influenza are people in whom our direct testing has been done so someone has taken a sample and sent it to a laboratory. This is usually not how we count deaths from influenza. If we look at the estimate for influenza deaths each year, these are really developed by looking at the death records in countries and applying models to them and then estimating how many of them are due to influenza. I think that this will take about a year, perhaps a little bit longer, after the pandemic ends, to actually make the same kind of estimates for this pandemic. And when we do that I think that we will find that in fact the number of deaths worldwide is much higher than the 10,000. To give you an example of this, if we look at the United States one of their surveillance systems is to look at the number of deaths going on right now above an estimated baseline of deaths. What they would expect to see if the pandemic was not going on. So for the 10th straight week they are reporting that the numbers of deaths are above the estimated regular number of deaths. I think that at some point when this kind of information are counted up through the usual techniques that we do then we will see that the overall number of deaths is quite a bit higher than the numbers we are talking about now. Thank you.

**Nyka Alexander:** Next question is from Dermot, Bloomberg, Geneva. Please go ahead.

**Dermot**: Hi, Keiji. What do you expect governments in Europe to do with all the left over swine flu vaccines now that so many people have been vaccinated already or rather not getting vaccinated in large numbers?

**Dr Fukuda:** I think that again I cannot second guess what countries will do with their vaccines if they have leftover vaccines. Again, I think that they have a number of options. For example, it could be provided to other countries that don't have vaccines; it could be used for later on. I think that again, as I mentioned in response to one of the earlier questions, this is a virus that we don't expect to suddenly just disappear. This is a virus that I think we will see in circulation again in the fall and in later periods of time so, again, I cannot second guess what countries are going to do but I think there are a number of options. Thank you.

**Nyka Alexander:** Next question is from Miriam Falco of CNN. Go ahead Marian.

**Miriam Falco:** Thanks for taking my question. Dr Fukuda, could you elaborate a little bit more on why those three countries - Azerbaijan, Afghanistan and Mongolia and other countries - why those first;  do they have cases already; once the two per cent of the population is set aside, would they be getting enough vaccines to actually vaccinate the rest of the country etc.? Thank you.

**Dr Fukuda:**  Thank you for the question. Again, in general, there were a number of factors that we have tried to look at. One of them is that simply countries, these are countries which as a group are not able to access vaccine in other ways unless they get the vaccine provided through WHO; Two, we have looked at the fact that there is more activity going on in the northern hemisphere and so people are more likely to be exposed to the virus in the northern hemisphere now. But then there are additional factors. One of the things that I did was mention that there are three steps that we are asking countries to do and these include things such as going over their national plan and demonstrating that they are capable of receiving the vaccine now and then administering it to the people. Based on those kinds of considerations, these are the first three countries that we are targeting to get the vaccine out to. Now, in terms of who else may get vaccinated, the WHO vaccine supply, the stockpile would be able to vaccinate up to about 10 per cent of people in this group of countries. We do not have the ability to provide vaccine to all people in these countries. However, I do want to point out that it is extremely important for everybody to understand that vaccines are one part of a larger group of disease control measures that countries and people can take to protect their populations. So, for example, we have antiviral drugs which are useful but we also have a number of steps that people can take such as the so-called respiratory etiquette steps to try to reduce the chances of infecting other people. There is guidance on staying at home if you are sick and so again you reduce the chances of infecting other people. So there are other steps which can be taken in addition to vaccines and antivirals and we continue to provide this kind of advice and guidance to countries to show them really that there are a range of options out there. Thank you.

**Nyka Alexander:** Next question is from Ms Rosera in Geneva - I am a sorry if I have the name wrong.

**Ms Rosera:** Hello and thank you very much for taking my question. I was wondering is the vaccine rate of developing countries very low and how do you assess this at WHO? My second question is how are you going to work to go up the  vaccine rate for countries? Thank you very much.

**Dr Fukuda:**  Could I ask for clarification when you say vaccine rate, do you mean for the pandemic vaccine or do you mean for seasonal influenza vaccine?

**Ms Rosaro:** I heard for example that in France on the on-line survey 78 per cent of the population do not intend to get vaccinated so I was wondering about the vaccine rate of the H1N1 for the population.

**Dr Fukuda:** Thank you for that clarification. I think that the job of public health is really to alert the public when there are significant dangers to which they may be exposed and then also to identify the options and the things that people can do to protect themselves against that danger. For example, with the pandemic situation, getting useful information, accurate information out to the populations is one of the basic jobs of public health and this is both true for the national groups as well as for WHO. One of the options for people, for example in France, is that they may choose to be vaccinated or they choose not to be vaccinated. Now, in this particular instance, WHO believes that vaccination is an excellent option to take to protect people against the pandemic influenza and the reason for this is that when you are dealing with infectious diseases, providing some degree of increased immunity against the infection is often the best thing that you can do to protect people against the infection. However, I think that in this kind of instance what WHO and the national authorities can do is to make the information available to people and then in the end provide guidance and our guidance would be that we believe that vaccination is an excellent option for protecting yourself. In the end, however, people will make their choices. Now we have seen that in different countries there are different experiences. In some countries we have seen that in fact there has been a demand for more vaccine and oftentimes the opinions of the population will differ depending on what the experiences in that country are about the pandemic situation. So, to summarise this, what WHO will do is to continue to provide information that we hope is useful and that is accurate for people to make their own decisions. We will make sure that the options for vaccination and the pros and cons of it are clear to people and then we will do whatever we can to facilitate the access to these vaccines. Thank you.

**Nyka Alexander:** We have a last question from Mr Stein of the Washington Post. Please go ahead.

**Mr Stein:** Hi, Dr Fukuda. Thanks very much for taking my question. I really have two questions. One is related to that question which is in which countries have you seen demand dropping or demand going higher or surging? The second question is what criteria will you use to decide when the pandemic might be over?

**Dr Fukuda:** I think one example in terms of countries is that Norway is a good example of the situation changing. I think that in Norway there were a number of people who died from pandemic influenza and this information really changed how the population responded to the availability of vaccine and the difference before the deaths occurred and afterwards. The fact is that there was quite an increase in the number of people who asked to be vaccinated so there is one concrete example. Now in terms of the criteria of when the pandemic is over - probably the way that the issue is really helpful to look at is that the question is terms of countries and in terms of countries and in terms of public health authorities is when is the right time to begin to back down from some of the levels of alert readiness that we are at in terms of dealing with the pandemic because it is unlikely that something like a pandemic just ends overnight. This is really going to decrease in different countries at different times in terms of levels of infection and the question that the scientific community and that the public health community is going to grapple with, is when is it probably safe enough for countries to back down on the kinds of protective steps that are being taken now. I think that it is a little bit difficult to say what the criteria are right now. What we will do is that we will end up consulting with the best scientists in a number of different disciplines so I think for this kind of question to get answered we will need to be in consultation with some virologists, who would be able to shed some information on how the evolution of the virus is progressing and how this impacts on our ability to look forward. We will be discussing and consulting with epidemiologists to look at disease patterns and try to get to the question of what is the likelihood that we may see another surge of activity in February, March, April something like that.  And in addition, we will be working with people in modelling community, again to try to take the current available information and see if we are able to get a better handle on of what we will be seeing in the next 3 or 4 or 5 months, again trying to answer if there's a reasonable likelihood that we will not see another wave of activity or we will see another wave of activity. And so once we get this kind of information, and these kinds of discussions, we'll have a much better handle of when is it time to back down from some of the readiness levels that we are at now. And so this is really the process and the kind of question we'll ask and the kind of people we'll hold discussions with. Thank you.

**Nyka Alexander**: Thank you Dr Fukuda, and thank you to all the journalists online. Just a few quick notes before we fully wrap.  To repeat Dr Keiji Fukuda's title: Special Adviser to the Director-General on Pandemic Influenza. I would like to remind you that there will be an audio file posted on our website shortly, and later today or tomorrow morning a transcript of the briefing. The web site is www.who.int; you can click on the "more information  on pandemic influenza", and on the right hand column there is a media link. This is likely our last briefing of this year until the new year, so we would like to thank you for all of WHO, thanks to the journalist for your interest, from the communications and from the studio team as well, happy holidays to everyone.

# Transcript of virtual press conference with Dr Keiji Fukuda, Special Adviser to the Director-Generalon Pandemic Influenza, World Health Organization

14 January 2010

**NYKA ALEXANDER**: Good afternoon. We welcome you this virtual press conference, today, January 14th 2010. My name is Nyka Alexander. With us is Dr Keiji Fukuda, Special Adviser to the Director-General on Pandemic Influenza. He will be giving a situation update, speak in more detail on some topics, and will then take your questions. Before he begins, let me clarify that there is indeed video available of today's briefing. Sorry about the error in the advisory. We have also prepared two sound bites and B-roll of Dr Fukuda which went out via EBU, for those of you who might be interested in that format please contact the communications team of you want more details on that. Dr Fukuda, over to you now. Thank you.

**Dr KEIJI FUKUDA**: Thank you Nyka. Welcome everybody to this virtual press conference. Now before I begin with the main topic of the day which is the pandemic,
I would first like to take a moment to note the very severe earth quake which has struck both Haiti and Dominican Republic. WHO wishes to express its profound sympathy for all of those who have been affected by the severe loss of life and the destruction in those countries. I know that there'll probably be a lot of questions about this event and if you have additional questions, please contact the communications team here.

Now what I would like to do today is again start off the conference with a very brief overview of the epidemiologic situation and then go into some of the main topics for the day.

In terms of the current situation, at this time the most intense pandemic activity continues to be in a couple of places in the world such as North Africa, in Southern Asia and then in parts of East and Southeast Europe. In other parts of the world, we see that activity is declining or has declined but we also continue to see in these areas a transmission of the virus, so it has not disappeared, and it is has not gone back to baseline. Based on the situation, our current assessment is that it remains too early to say that the pandemic is over. This is because we continue to see continued activity at elevated levels in a number of countries. And because it is unclear whether we will see in the northern hemisphere over the next few months during the winter and spring period another significant wave of activity and also because we do not know yet what will happen in the southern hemisphere during its winter months. So for these reasons, we consider that the pandemic is still ongoing.

Now, as an international health institution which deals with major global health events, WHO understands that it is the subject of criticism and questioning about what it may have done, and in this respect, we really welcome this when it is constructive, because it significantly helps us to improve how we do things. Now recently we were asked by the Council of Europe to participate in hearings about pandemic influenza, and we welcome this opportunity to talk about the pandemic, to provide accurate information and to clarify misconceptions. However, since there are still some misconceptions circuiting among the media, right now, what I would like to do today is address some of this directly and some of the questions which have been coming to us in the recent number of days.

The first question that I will talk about is whether this is a real pandemic, the second one is, did WHO change its definition of the pandemic, the third topic is, did WHO overplay the pandemic and the fourth issue is, was WHO unduly influenced by industry.

So let's go to the first question: is this a real pandemic.

Here the answer is very clear: yes.

The allegation by some, that the H1N1 pandemic is a fake is both scientifically wrong and historically inaccurate. Let me start by going through some of the basics, so I can provide you with the context for why we can say this so clearly. With infectious diseases, scientists often talk about groups of infections, and they use different terms. So for example, when we talk about a small number of people being infected, we may use the word cluster, or we may use the word cases. And then when we're dealing with something larger, we may be using words, such as outbreak or epidemics. Now these are not precise terms, but they give you a sense of a relative difference in size. When we talk about the largest size, which is involvement of most of the world, then we're talking about a pandemic. If we look specifically at the H1N1 pandemic, we can see that WHO was first notified about human infections in late April. At that time we had laboratory information which told us that this influenza virus was genetically and antigenically very different from the normal human influenza viruses circulating around the world. We had epidemiologic information which was provided initially from the North American countries Mexico, Canada and

USA, which demonstrated convincingly that there was person to person transmission occurring at the start. Then we had clinical information, especially coming from Mexico, which told us that this virus could cause severe or life-threatening infections. At that time these reports themselves did not tell us that we were in a pandemic situation, but they did send a very strong warning to public health authorities around the world, including WHO, that we should be ready for a pandemic.

So let's go to some of the sequence of the events at that time. On 29 April 2009, WHO reported confirmed infections in 9 countries. About 6 weeks later, on 11 June, WHO reported that laboratory confirmed cases were being reported in 74 countries and territories. Just a few weeks later, on 1 July, WHO reported that there had been confirmed infections in 120 countries and territories around the world. It is this global spread which led WHO to call for increasing phases as we proceeded, and also to eventually tell the world that a pandemic was definitively under way.

So at this point, let's not play word games, and let's not be indirect about this matter. This is a new influenza virus that emerged in 2009 in North America. At the most conservative count that we have, we estimate, we believe, or we know that about 13,000 people had been killed directly by this virus. When final estimates are made, for the world, at some point in the future, we anticipate that these figures will be much larger that what we see now. The allegation that this is not a pandemic is scientifically wrong and is historically inaccurate. I also want to note in passing that it is somewhat disrespectful, for the many people who were affected by the serious illnesses caused and for the deaths that were caused by this influenza virus, as well as to the very large number of people in all countries who have been working around the clock to protect others from this pandemic.

Now let me move on to the second issue. Did WHO change its definition if a pandemic? The answer is no, WHO did not change its definition.

So again, let me provide a little bit of context here for this answer. Let me start by pointing out that there are many sources that any of you can go to, to look up the word pandemic, and find the definition and you can find these in textbooks, you can find these simply by going to the web, and typing in 'definition of pandemic'. What you'll find is that definitions are sometimes worded somewhat differently but all of them basically agree that the pandemic is a worldwide spread of an infection or a disease. Now different diseases can have different features when they cause a pandemic. A pandemic of HIV/AIDS for example has features which are very different from a pandemic of influenza. And even when we look at influenza pandemics, we can see that there are significant differences between the pandemics, for example, the pandemic caused by the 1918 virus, resulted in the greatest number of deaths that we know of, and more than what we saw in

1957 or 1968, as well as 2009. But the basic idea is the same: there is the world wide spread of a disease. WHO has consistently emphasized this concept in these definitions.

The formal definitions of pandemics by WHO can be seen in the guidelines which have been provided to countries. Now these guidelines were first developed in 1999 and then updated subsequently in 2005 and then in 2009. And when you look at them you will see how the many hundreds of scientists who work with WHO on these definitions and on these guidelines really tried to improve the definitions to make them clearer from the guidelines. One of the things that WHO did not do in any of these definitions was make severity part of the definition. And the reason for this was very simple: when we look at history to tell us, that the impact of pandemics can range from being mild up to very severe. We know that, and so we know that when we see the spread of these new infections, that the impact of the pandemic may eventually vary from one extreme to the other extreme. So the documents are technical, but I really encourage you to look at them to see what the definitions really have said.

Now let me go to the third issue: did WHO overplay the pandemic? The answer here is no, it did not. I would like to refer you back to the speech given by the director-general, Dr. Margaret Chan, when she first announced the pandemic. In that talk to the world, what she said was that we had reason to believe that the pandemic would be of "moderate severity".

Now from the very beginning WHO has gone out of its way to let everybody know that the future course of the pandemic was uncertain, that we did not have a crystal ball and could not tell you at the beginning, which way it was going to go. This remains as true today as it was back then. It is true, however though, when we're at the start of a new health threat, and particularly when there are so any unknowns, that often times the public and the media can react very strongly to the emergency of such a health treat, that at the time and all through the pandemic, WHO has been very consistent in the information that it has given.

Now given this reality there is no health authority, including WHO, which can afford to sit back before making decisions, and actions have to be taken, because we have to provide support to countries and other institutions, working to reduce the impact of the situation. In providing this information, WHO has always been very balanced and I think sober in providing its assessments. We've worked very hard to neither overplay, nor underplay the situation and we have worked very hard to try to reduce confusion, rather than to create it. Now, since we have always known, and have repeatedly said, that pandemics can range from mild to severe, we have also pointed out that the severity can change midstream. And given this situation, WHO and other responsible health authorities have adopted a precautionary approach – that is, we have tried to prepare everyone for the worst and to hope for the best.

So at this point, I think that the health impact of this pandemic can fairly be said to be moderate compared to the health impact of some of the pandemics in the past. But I also want to point out that the means and the actions taken by countries to deal with this pandemic have been by far the best in history, We don't know how many infections and death have been avoided or prevented by the actions taken by countries and we don't know how much these efforts have helped mediate the overall effect of the pandemic, but we firmly believe that these effort should not be discounted.

Now, I would like to go to the fourth issue: was WHO inappropriately influenced by the pharmaceutical industry? And the answer here is no.

Now, again, let me try to provide some context. When WHO responded to the pandemic, one of the things we did as soon as possible was to reach out to a wide variety of experts and sectors around the world including industries. We had discussions with them on a variety of topics, and with the industry representatives, we talked both about vaccines and vaccines viruses and what could be done to expedite the production of vaccines as quickly as possible.

Now the question is not really whether we had contact with the industry, but whether we had any undue influence exerted upon us by commercial interest. And the answer is no. WHO has long recognized that in reaching out to such a broad group of experts and interest groups, that there is a risk for potential conflicts or interests in the advice which is provided to the organization. So to protect the integrity of the advice which was given to WHO, to remain free from any undue influence, WHO has had in place routine safeguards against potential conflicts of interest in the advice given to WHO. This is really a longstanding practice and is true at all times, and certainly well before this pandemic, but also during this particular pandemic.

Now WHO requires the experts, who provide advice to the organization, to declare all their professional and financial interests including funding, which is received from pharmaceutical companies, or consultancies, or other forms of professional involvement with these commercial interests. This information is then shared with other members, shared within the institution to look at them for appropriateness, and then if the person is part of an advisory group, it is shared with other members of the advisory group and it is taken into account by WHO in determining whether the experts concerned should continue to provide advice to the organization.

Finally here I'd like to note that any allegations of undeclared conflicts of interest are taken very seriously by WHO and we respond immediately and appropriately to them.

So in passing let me just make or end with one other point, and this is, we have received some questions, about whether WHO will be undergoing a review process and the answer is yes, we will be conducting a self review along with others of what happened during this pandemic. Now similar to almost any organization which is concerned with the quality of its work, WHO assesses its performance during major experiences and then works to learn from that, so-called lessons learned, and then to take those lessons learned and to improve from it. Now in this instance, WHO and the countries in the world operated under the International Health Regulations. Now the International Health Regulations call for an evaluation of how well the regulations have been implemented and so WHO will use this opportunity to begin an evaluation of its own performance.

So at this point, let me conclude again with just three short remarks.

In the first place I want to emphasize the world is going through a real pandemic. The description of it as fake, is both wrong and is irresponsible.

The second point is that WHO has been balanced and truthful in the information it provided to the public. It has not underplayed and it has not overplayed the risks of the pandemic.

The third point is that WHO has reached out to all parties who could help to reduce harm from the pandemic but we did take very great care to make sure that the advice received was not unduly influenced by commercial or non-public health interests.

So with that, let me stop here and then I am happy to take any questions you may have.

**NYKA ALEXANDER:** Thank you, Dr Fukuda, thank you very much. Before we go over to questions, may I remind you that an audio file of Dr Fukuda's briefing will be available immediately afterwards, in the Media Centre section of the WHO web site and a transcript will be available a few hours later. To ask a question, please type 01 on your keypad to get in the queue. The first question is from Martin Enserinck, Science magazine. Please go ahead.

**Martin Enserinck, Science**: Could you be more specific about the review that you mentioned, you were talking about a self review. What does that mean? And wouldn't it be more appropriate to have some kind of independent outside team to look at how this was handled.

**Dr KEIJI FUKUDA:** Thank you Martin, and let me clarify here. The International Health Regulations call an agreement among all member states for which WHO acts a kind of a secretariat for the International Health Regulations. And those regulations call for a review of how the regulations themselves have been implemented. And given that we have gone through such a major experience over the past several months, and continue to go through it, we have decided that this will be a very good opportunity to use this assessment to look, begin to look at the response to the pandemic.

So the assessment itself, of course, will involve many people who are unrelated to the IHR, or who are unrelated to WHO. These will be people who are not part of WHO but who will be asked to conduct the assessment and conduct the review of the pandemic and our performance. And so in that sense, it is really not a self-performed evaluation. It will be done by others. But what I meant in my comment was that, we recognized that we need to use these opportunities really to improve our own performance, and in this regard, WHO is really pushing for this kind of evaluation to be done. Thank you.

**EVA CRUZ, SPANISH PUBLIC RADIO**: I am asking about the particular case in Spain, I know it’s the same in other countries. Spain bought 37 million doses of vaccines of which only 13 million have been used. Is there, will there be any measures put in place, in order to save money in this kind of prevention strategy in future. What can we learn from the excessive buying of theses vaccines?

**Dr KEIJI FUKUDA:** This is a very good question. The decisions by countries to, whether to buy vaccines and then how much vaccine to buy have really been decisions made on country by country decisions basis. WHO was not asked by these countries to provide advice on those kinds of decisions, and has not taken part in any of these discussions.

I do want to point out, however, that the public health authorities involved in these discussions, really have a very difficult task when they are facing questions about how much vaccine for example to purchase.

Now at the beginning of the pandemic and during much of the pandemic, it was really not clear what the ultimate impact of the pandemic would be. How many people might die, how many people might suffer serious illnesses from it and so on. And in that kind of uncertainty, the health authorities still had to go ahead and make decisions about what to buy. And so I think it is really impossible to second guess the wisdom of these decisions. And I think that at the time these decisions were made, I am sure that the top consideration was that, "what needs to be done to reduce harm from the pandemic."

Now I think that at this point, again, I want to point that the pandemic continues. If the pandemic virus changes and we begin to see much more serious illness from infections, it is quite possible that countries will also be asked why they did not buy more vaccines. So I want to point out that this is a very difficult decision that has to be made in the face of not having all the information that one would want to have. Thank you.

**HELEN BRANWELL, CANADIAN PRESS**: Hi, if I could ask a couple of questions.
Dr Fukuda, you were talking about the review in answer to Martin's question, I was wondering if you could tell us what will happen with any report that comes out of that process will be made public, how does WHO go about sharing the findings of that.

The other question was when you were talking about the suggestion that the pandemic definition had been changed. You said that, you talked about the fact that there has been series of iterations. I think you said that severity was not removed from it but I thought it was in an earlier iteration? Is that not true.

**Dr KEIJI FUKUDA**: Thank you for the two questions. So that let me first go to the IHR.

One of the first things that will happen is that the executive board of the WHO will be meeting next week, and so this idea for an assessment will be run by the board. And there will be discussion, and I think that we will receive guidance from the member countries, as to how to conduct some aspects of the assessment. Now I am sure that the results of such assessments will be made available. I cannot tell you at this point how and when this information will be made available. But of course this will both be useful to WHO but also to a number of other organizations and countries. And so I anticipate that the findings of such an assessment will be available.

Now in terms of the pandemic definition, I think that there has been a lot of confusion, because there have been a number of different documents which have talked about pandemics. Now some of the documents which have been put up, have been descriptions of pandemics, and particularly, some of the descriptions of potential pandemics were put up during the time when the concern about the Avian H5N1 infection were very strong. And I think in some of these descriptions, for example, one which is posted back in 2005, there was an emphasis on the more severe potential impact of a pandemic. And I think that some of the people have gotten this confused, have confused this kind of description with the definition of a pandemic.

But when you go back to the guidelines, and there were guidelines produced in 1999, 2005, and 2009, you will see that although there is discussion about these pandemic definitions and there is some continual attempt to try to make them clearer, severity itself was not part of the definition. Thank you.

**Debora MacKenzie, New Scientist**: We have been seeing a lot in the press in the last little while, commentaries of various kinds saying, 'Oh well, it was not very much, it was ordinary flu'. Obviously that is not true as you have said. But there is a feeling out there, right or wrong, that was an awful lot of alarm, and a lot of vaccines bought, and then it did not turn out to be much. Do you think that there is now a chance that there could be a backlash and this could harm future efforts to prepare for flu pandemics and other kinds of health events and is there anything you would like to say about that?

**Dr KEIJI FUKUDA**: I think that in this kind of situation, the greatest danger is from a lot of misinformation being passed, and I think from misperceptions about what was done. So again, what I want to state and be very clear about is that at the outset of the pandemic, when the public health authorities around the world were dealing with this situation and facing many unknowns, this is when they had to make a lot of the decisions about what to do. And this is when many of the hardest decisions were coming up during the pandemic. So I think that, in general, what health authorities, including WHO, most strongly hold forth as the most important goal is to make sure that everything can be done to protect people from harm. So in this situation, I think that this is an application of the so-called precautionary principle: prepare for the worst and hope for the best. And so here, what I hope for is that people understand that the decisions that were made were done in a very sober light. They were done recognizing that the pandemic could be more on the mild side and could be on the more severe side, and that the decisions that were taken were really very prudent, trying to take all practical steps and practical decisions that could be made to minimize the chance that people will be harmed. And so I think that if people understand this, they will understand that their governments by and large, were making the decisions that have to be made when you are facing a new global health threat.  Thank you.

**MARTIN, DUBLIN, IRELAND**: Dr Fukuda, you talked about the conflicts of interest, and as WHO requires people to clear any conflicts of interests. Has there been any case in the past with WHO, where they have disregarded the opinion because of a very obvious conflict of interest?

**Dr KEIJI FUKUDA**: Martin, you know, the conflicts of interest are identified by a variety of means, and then these are sometimes brought up within specific advisory groups. For example we have an advisory group called SAGE, which is the Strategic Advisory Group of Experts, which provides guidance and advice to the DG on immunization practices. And so there may be instances among some of these different kinds of advisory groups like that, but I would have to go back and ask whether we have any specific instances. More frequently is the situation where a potential conflict of interest is identified and then after assessing the situation, a decision is made as to whether there is a real conflict of interest or not. So we can come back and find specifics, but in general this is what is done. Thank you.

**EL MUNDO:** I would like to ask you concerning the group of experts that is going to evaluate the WHO overplayed concerning the pandemic. Who is going to name this group of experts? Please.

**Dr KEIJI FUKUDA**: So the IHRs provide guidance. Again, the IHRs are basically the rules established by all of the member states of WHO, 193 countries. And these are the rules by which the members will be selected to conduct the reviews. So we will follow those regulations. Thank you.

**ANDREA GERLIN, BLOOMBERG:** Can you tell us whether WHO is submitting testimony to the Council of Europe or making any response towards attending plenary session where they are going to discuss some of the issues they have brought up, I think on January 28?

**Dr KEIJI FUKUDA**: WHO has been invited by the Council of Europe to participate in a hearing on 26 January. And so right now, we are trying to find out the particulars of what the invitation actually means, and so we have not been told exactly what the participation means and what is being requested of WHO. Otherwise, we have not been invited to attend any other meetings, or any other events sponsored by the Council of Europe. But we are looking forward to participate but we do need more details from the Council of Europe. Thank you.

**JOSEPH, THE SUN**: Dr Fukuda, there are countries that feel that they have an overload of vaccines, or vaccines that they no longer need with the impression that the pandemic is already a spent force. They are trying to sell off their stocks, and how do you advise them? Another question - this misconception of the pandemic being 'much ado about nothing', how is the WHO going to re-educate the world community that it is indeed a major pandemic out there.

**Dr KEIJI FUKUDA**: In terms of your first question about advice the countries about their pandemic stocks. Again this is not a question which countries are coming to WHO and asking for advice about. These are generally decisions which are being weighed and discussed by countries because it is their vaccines and they are the ones who have to make decisions about it. And I suspect that different countries may come up with different decisions. So at this time, WHO is not being asked to provide advice and we are not providing any guidance on what to do with the vaccines stocks. However, at this time, WHO is still emphasizing that vaccination is a very important part of addressing the pandemic. There are still large numbers of people out there who are at high risk of serious complications from this infection. And again this includes people who are women who are pregnant. This includes people who have a variety of chronic medical conditions. These are the people who have; in general, developed the most serious complication from the infection. And that continuing to vaccinate these people is one of the best things that can be done by a country, if it has vaccine available. So this is one point that I would like make very clearly and very strongly.

Now in terms of your second question about what does WHO, what does an organization like WHO do to try to address the point about whether this is a real pandemic and to educate people. And so there are a variety of things that we do.

One of the most important is to reach out to the media and to talk with you, in discussions like this, with the hope that you will be part of getting the information out there, getting real information out which is accurate, and hoping that you will help to combat some of the false information and some of the misperceptions out there. In addition, we continue to work with a variety of different groups, and provide information directly through things such as the web, and through documents, and through interactions at meetings. So we will continue to do all of these things, and we will continue to provide as much good information as we can. Thank you.

**THE INDEPENDENT, SOUTH AFRICA**: My question has largely been answered by the previous journalists. I also wanted to know that with countries reducing their vaccines, whether pharmaceutical will be trying to offload those vaccines in African countries instead. And I know you said that the WHO doesn’t get involved in advising governments in what quantities of vaccines to buy but I also wanted your opinion on whether African countries should be wary of this kind of offloading.

**Dr KEIJI FUKUDA**: Let me point out some important things which WHO has been involved in which directly involves Africa to address this point.

Now some months ago, in fact, one of the most important things that the DG did in concert with the Secretary General of the United Nations was to make a call for global solidarity, that is, for the countries that had vaccines, for the richer countries to help out other countries that did not have access to the vaccine. This took place many months ago and was repeated, and because of these calls for action, one of the things that happened was that a number of countries as well as some of the commercial companies donated vaccines to WHO; pledged vaccines to WHO, as well as some of the ancillary supplies such as syringes and safety boxes and so on, to try to get vaccines to countries that don't have access to these vaccines, largely lower income to middle income countries that without this kind of support would not have access to vaccines. We continue to work on this. Many of these countries, of course, are located in Africa and we will continue to try to get vaccines to them in as rapid a manner as is possible. So we believe that the vaccine in a pandemic situation can be used to protect people who are at high risk from complications and we hope we can push ahead with this effort.

**Nathalie**: I talked to people from the Council of Europe and they said that WHO does not want a public debate on the 28th or 26th, and that you have asked for a session behind closed doors. I wanted to know whether that was true. And also, second question, about the vaccine. I see that some contracts with the industry about the vaccine production were already made in 2007 after the bird flu, and that part of these contracts was that the companies would produce vaccines when a pandemic would arise and that the governments would pay them. There was no real option for cancelling it. So I think that might be one of the problems here, and I would like to have a reaction to that.

**Dr KEIJI FUKUDA**: OK; thank you for the two questions.

In the first question, let me be very direct and very clear. The Council of Europe has not asked WHO whether it prefers an open door meeting or a closed door meeting, and WHO has offered no request to the Council of Europe for a closed hearing. We were expecting that this might be an open hearing, but WHO definitely has not asked for a closed hearing. This is not true.

Now in terms of the second point and the vaccine contracts. Again, WHO has not been privy to any of the contract discussions between countries and the companies. These are considered proprietary discussions both by the individual countries themselves as well as the companies. So we do not have knowledge of the individual contracts which are made between countries and companies. However, I think it is fair to point out that the pandemic preparedness planning for pandemics have recognized that vaccines, if available, would be an important part of the response against a pandemic, and would be one of the better ways to try to prevent people getting infected by a pandemic influenza virus. And so I would not be surprised for the discussions and pre-planning done by countries or companies as part of the general thinking about preparedness for a pandemic. But again, I cannot comment on any of the specifics because we simply have not been privy to the information.

**NYKA ALEXANDER:** That's all we have time for today. I apologise to the journalists who were not able to get their questions through…. This has been the virtual press briefing from WHO Headquarters with Dr Keiji Fukuda, Special Adviser to the Director-General on Pandemic Influenza. I would like to remind you that there will be an audio file posted on our website shortly and later today or tomorrow morning a transcript of the briefing. The web site is www.who.int/pandemicflu. Thank you again, and have a good day.

# Transcript of virtual press conference with Dr Keiji Fukuda, Special Adviser to the Director-General on Pandemic Influenza

11 February 2010

**Gregory Hartl:** Good afternoon. This is Gregory Hartl from WHO headquarters in Geneva. With us is Dr Keiji Fukuda, the Special Adviser to the Director-General for Pandemic Influenza, and we will now hand over to Dr Fukuda who will begin by making some opening remarks about the epidemiological situation in general plus some upcoming events then we will open it to questions from you. So once again, welcome and over to Dr Fukuda. Thank you.

**Dr Keiji Fukuda:** Thank you Gregory, Welcome everybody to the virtual press conference and thank you for tuning in. As we have usually done these press conferences what I will do is first go over some general aspects about the current situation and then go into a couple of topics and then we will throw it open for questions.

In the first part, I want to go over the current epidemiology which indicates that activity continues in some parts of the northern hemisphere. So for example we are seeing that the highest levels of activities continue to occur in Northern Africa, parts of eastern Europe and parts of eastern Asia, as has been true for the past few weeks. In addition we are beginning to see some new areas of activity that we have not seen before.

So, for example, we have had reports of cases of infection occurring in Western Africa but more recently we have received the first reports of community infection or community transmission occurring in countries like Senegal.

But overall we are seeing a declining pattern of infections occur in the northern hemisphere and at the current time the number of laboratory-confirmed deaths continues to be over 15,000 cases. So if we look at this situation and we ask ourselves where are we, I think that it's fair to say that we are seeing an overall declining pattern in activity in the northern hemisphere or we appear to be. However it's also very clear that the virus has not disappeared and that it is continuing to cause disease and deaths in many parts of the world.

As I mentioned earlier for example we have now seen the first evidence of community transmission occurring in Senegal. I have discussed in earlier reports that Western Africa is one part of the world in which we have not seen much activity. So for WHO, this is an important piece of information.

This overall pattern suggests to us that we may be seeing a general decline in pandemic activity but that the pandemic itself has not yet run its full course and in some locations - not all locations - but in some locations - we can expect to see that community outbreaks can be expected to occur in the near future or in the future at some point.

Now because of this situation which is different than what we are seeing say some months ago, WHO will be asking the Emergency Committee to convene later this month to review the situation and provide WHO with guidance on whether we are entering into a so-called post-peak period. In the Pandemic Preparedness Guidelines which were developed between 2007 and 2009 and provided to countries for preparing for pandemic influenza, the post-peak period is really described or is in essence a transition period in which pandemic activity may be continuing at various levels in different parts of the world or in different countries. But there may be some evidence that the highest levels are now past us. To be very succinct here, what we are hoping for is that the worst is behind us and that we are on a general decline in activity but we still do see that there is significant pandemic activity in some locations and we do want to point out that even if we are entering into a period of general decline, we can anticipate that in some locations there could be significant local upsurges of activity. This is an important point to remember.

The emergence and spread of the new pandemic virus has been very well documented scientifically and we saw that associated with this spread there were for example unusual summer outbreaks of activity in many countries and we saw that there were unusual patterns of severe illness and death occurring in younger age-groups. At this point the virus has spread to most countries in the world and so we hope that an overall decline is being seen although again I want to point out we have to expect that we will see some local outbreaks occur and some local upsurges of activity to occur.

The 2009 Pandemic Preparedness Guidelines anticipated at some point that there would be a transition out of a pandemic period but the world would not have reached a normal state in which we would be fully back into seasonal influenza patterns that we normally see in a non-pandemic period and this transitioning period where the pandemic activity continues but may be tailing down was really called the post-peak period. Again, the post-peak period can be considered a transitional period in which the pandemic is continuing but there is a scientific judgement that the worst, on a global level, is probably over - again even though there may be some local outbreaks occurring or local upsurges.

One of the questions which has come up about the post-pandemic peak period is why is the transition period over? Can you not just say that the pandemic is over and declare that? When the scientists who worked on this - and there were about 138 scientists from over 45 countries who worked on this for quite a long time - considered the situation they really indicated that the ending of a pandemic cannot be considered an abrupt on or off situation, that there would inevitably be a transition period in which we would see that the patterns of influenza activity would be different in different countries. So for example in some countries the activity may be very low while in other countries we may be still seeing significant community transmission as we discussed earlier in this report. I think that the designation of a post-peak period or a transition period is really a way of helping national authorities to look ahead to the future and to begin planning, but also to make sure that they know that local outbreaks and upsurges can be anticipated in places and that appropriate steps still need to be taken.

In closing here, I want to simply say that WHO will continue to work very closely with the countries in providing recommendations on what to do during a transition period. As I mentioned earlier, we will be discussing the situation with the Emergency Committee later in the month and asking them for their guidance on whether we have indeed entered into a post peak period.

Given this overall situation, one of the additional activities that I wanted to highlight was that as we see the unfolding of the pandemic continue, WHO continues to work on many of the activities which have to go forward to deal with influenza and this would be true whether we are dealing with a pandemic situation or whether we are dealing with a regular seasonal situation.

Next week, WHO will be convening a meeting to decide which strains should be recommended for going into the northern hemisphere influenza vaccines. We hold these meetings twice a year, one for the northern hemisphere and one for the southern hemisphere and these meetings are held quite often - much more often than for other vaccines for the simple fact that influenza viruses change very often and we need to conduct these analyses on a frequent basis and these meetings on a regular basis in order to keep up with these changes.

The strain selection meeting for the northern hemisphere will begin next week, as I mentioned, and on the 18th there will be a public meeting at which the recommendations of the advisers to WHO will let it be known what the recommendations are for the upcoming northern hemisphere influenza vaccine.

In reality, the work of choosing these strains really goes on year round. It does not just take place at this meeting. There is a great deal of work which goes on before these face to face meetings. But twice a year WHO brings all of the advisers and also some observers together for a face to face meeting and the purpose of that consultation is to finalize analysis of genetic and antigenic data and also to take into consideration any relevant clinical and epidemiologic patterns to help choose the best strains to go into the influenza vaccine. In these meetings there are advisers to WHO and there are observers in the meetings. The advisers are the ones who make recommendations to WHO and these are representatives of the relevant WHO Influenza Collaborating Centres also from a group of national regulatory agencies that we term the Essential Regulatory Labs.

The observers are often directors or representatives of national influenza centres, these are the laboratories which provide the data for these analyses and also from academic centres and sometimes other partners.

Following the discussions and the in-depth analyses which go on for a few days, there is a public meeting at which the strain recommendations are announced and this information is made simultaneously available to the people in the room and it is also posted on the web. So this information is waited for by the vaccine manufacturers so it is made available to all vaccine manufacturers making vaccine everywhere in the world at the same time.

At the same meeting, there are often questions which come from the audience and so there is a back and forth between the advisers and the people sitting in the audience. What I want to do is close out here and point out that this is one of the activities that we conduct on a regular basis in order to meet the challenges of influenza both seasonal and pandemic. And I also want to highlight the fact that this is one of the key ways in which the public sector and the private sector work together on global health problems. This kind of collaboration is really essential for dealing with a disease like influenza because the information comes from countries through their monitoring and assessment activities and then the vaccines come from the private sector because that is where the manufacturing capacities are. What we try to do is facilitate and make this process as effective as possible. With that let me close the talking part of this and then we can go on to the questions and answers.

Thank you.

**Gregory Hartl:** Dr Fukuda, thank you very much for those remarks. Before I open this up for questions, just a couple of reminders to you who are listening, if you would like to ask a question, please type 01 into your keypad and that will put you in the queue. And secondly to remind you that an audio transcript of this briefing will be available immediately afterwards on our web site www.who.int. and a written transcript of this briefing will be available later. Thank you very much and first in the queue is Frank Jordans from Associated Press in Geneva.

**Frank Jordans, Associated Press:** Hello Dr Fukuda. I have got two questions, first of all a clarification on this transitioning period. If I understand you correctly the Emergency Committee is going to meet later this month and it's going to decide whether the pandemic has ended - what you are describing as the post-peak period - so if they decide that is the case that means basically the pandemic is on the way out. The other question is whether you think it is likely that the H1N1 strain will be added to the seasonal vaccine.

**Dr Keiji Fukuda:** Thanks Frank for the questions. As you know the Emergency Committee is a Committee which is created under the International Health Regulations to provide guidance and advice to the Director-General so what we will do when the Emergency Committee meets is to provide them with any information that they request in order to assess the epidemiologic situation and then what they will do is that based on the review of that information and any other input they decide to take into account that they will then make a recommendation to WHO as to whether they think that we are entering into a transition period or a post-peak period. That is one of the things which will occur. In terms of your second question, is it likely that the H1 virus will be in the upcoming season's vaccine. Again, I do not want to second-guess what the experts advisors will recommend at the strain selection meeting. However, I think it is fair to point out that the current pandemic virus, the H1N1 virus, is by far, the most common virus being isolated for influenza viruses around the world. It shows no signs of disappearing and that, and that there is very good bet that we will expect to see this virus around for quite awhile. So it is I think easy to guess that the experts who will be really be looking at this viruses, one of the virus for which the vaccine has to protect against. Thank you.

**Gregory Hartl:** Dr Fukuda, Frank thank you. The next question is from Richard Knox of National Public Radio, go ahead.

**Richard Knox, National Public Radio:** Hi, thank you very much. A couple of things. I wonder if you could talk a little bit about what the surveillance is showing most recently about the other flu viruses out here H3N2 and B flu and whether there is still stability in the pandemic virus as far as you can tell.

Secondly, I wonder if you could comment a little bit on the utility of having some of this leftover pandemic flu vaccine that might be re-deployed in the next seasonal flu vaccines.

**Dr Keiji Fukuda.** Thanks Richard. I will take this question as they came up.

Worldwide, we have seen that over the emergence of the pandemic virus, that this virus quickly became the predominantly virus in essentially in all parts of the world. So if you look in some parts of the world, it is virtually all viruses have been pandemic viruses. However, the seasonal virus is so far have not completely disappeared. So we have continued to see for example, H3 and 2 viruses be isolated in some places. And more recently, we have seen, you know, a fair amount of B activity, so B viruses being isolated. So I think that it is fair to say that the H1N1 virus has been by far the predominant virus. But the seasonal viruses have not disappeared and they still continue to cause some infections.

Now in terms of the stability of the pandemic virus, there have been some pandemic viruses which have been so called low-reactors, that is viruses which are somewhat different from the viruses that have typically been circulating. But it is fair to say that by far, most of the viruses which have been characterized, really the vast majority of them, have really been similar to the viruses which are contained in the current influenza vaccine. So to that extent, I would say that there is still a great deal of stability among the pandemic viruses. Again it will be interesting to see how this continues into the next year, because we typically see that these viruses, influenza viruses, change and mutate over time. But right now, we still continue to see a fair amount of stability in the pandemic viruses.

In the terms of the utility of pandemic vaccines at this time, we continue to see that this virus causes infections. We continue to see that this virus continues to cause death. And we continue to see that in some parts of the world, there is a significant levels of infection going on. So while this situation persists, and while we consider that people are at risk for severe disease from this virus, I think that it is still an important part of the way for people to be protected against this infection. So there is still a great deal of continued utility for this vaccine. Thank you.

**Gregory Hartl:** Thank you very much. The next question is from Kate Kelland from Reuters, please go ahead:

**Kate Kelland, Reuters:** Hi, I have two questions. Could you give us a date for the meeting of the Emergency Committee, please. And the second question is on west Africa, and the places where you describe as seeing bubble of infections going on. How well prepared and able to cope are these areas where the infections are still looking significant?

**Dr Keiji Fukuda:** Thank you Kate for the question.

The specific date for the Emergency Committee meeting has not yet been set. It is probably going to be in the last week of this month. But the specific date is not yet set.

In terms of your second question, how well is west Africa prepared. I think that it would be fair to say that in some ways, they are better prepared than in some countries which were infected earlier. There is a great deal more information about the pandemic virus, and I think that the communications and the information provided about the patterns of disease, has been helpful for the countries in west Africa in their preparations. On the other hand, we again have yet to see what patterns of disease may develop there, and I expect that if there are numbers of severe cases as in other countries, this will again cause some difficulties and stress for the clinical system. So right now we do not have any evidence of any unusual patterns in western Africa. But as I did mention earlier, these are new reports, and so we will see how this situation develops. Thank you.

**Gregory Hartl**: can I remind journalists once again please to dial 01 on their keypad if they wish to ask a question. And also to remember to consult www.who.int afterwards for both a written transcript and an audio file of this briefing.

So now to the next question which is from Miriam Falco, from CNN, go ahead please.

**Miriam Falco, CNN:** Two questions. You broke up a little bit when you were mentioning the number of deaths worldwide, If you could repeat those please. And then also, this evidently continuing controversy that WHO and other national health agencies drummed up that the H1N1 fear to help vaccine companies, to make more profits. Could please address that? That seems to be something that is simmering and does not want to go away.

**Dr Keiji Fukuda:** Miriam, let me address the first question. The number of laboratory confirmed deaths is over 15,000 right now. So these are deaths which are counted one-by-one and tested individually. In some of the earlier press conferences, I have mentioned that, I do not expect that we will know the real extent of death for another 1 to 2 years, after the pandemic. And this because the way that the overall number of deaths is estimated for pandemics and for larger events by using models, using death data from around the world. And so that kind of analyses will not be available. But currently, the laboratory confirmed deaths is over 15, 000.

Now in terms of the controversy about whether this is a drummed up pandemic, our perspective, and our position is very clear. This is a very well documented phenomenon in which a new influenza virus, which originated from animal influenza viruses, became infectious for people and spread around the world. It was really associated with epidemiologic patterns, such as high levels of summer infections that we do not typically see. And it also led to patterns of death and illnesses that we do not normally see.  So for example, most of the deaths have occurred in younger age groups. Many of the severe illnesses and deaths have occurred in people such as pregnant women and people with chronic diseases in younger age groups. And so again these are very different from we have seen from seasonal influenza.

Now when this event started, back in April of 2009, WHO worked very closely with Member States, to take the steps which were prudent, that is to provide communications to countries. To provide guidance on the steps that could be taken, and really to update them on the situation as it went forward. And in addition to that, WHO took all of its efforts possible to facilitate steps to protect people. So that is to make things such as recommendations on control measures, such as what individuals could do to protect themselves, what individuals who are infected could do to help prevent spread of infection in communities, and what communities could co in order to reduce the infections in communities to take place. And so really a number of steps that had nothing to do with either pharmacologic methods, but were really bread and butter epidemiologic principles aimed at preventing infection.

But in addition, WHO did take a number of steps to facilitate access of countries, particularly, developing countries to things such as antiviral drugs, and influenza vaccines. So for example WHO worked hard and very early on in the pandemic, made it, made antiviral drugs available to about 122 countries, which did not have access to these drugs. And also it continues to work very hard to make vaccines available to developing countries who have requested help from WHO for access to these vaccines.

So again, our position is very clear. This is definitely a true pandemic. The full magnitude of the pandemic is not clear at this time. But we see very clear evidence of severe illnesses and deaths occurring, and WHO will continue to take all of the steps that it can take to reduce the harm from this pandemic. So our position is very clear. Thank you.

**Gregory Hartl:** Dr Fukuda, thank you. The next question is from Alexandra of Agence France Presse.

**Alexandra, Agence France Presse:** So I wanted to have a bit more details about the Emergency Committee meeting. The assessment of the post-pandemic, what does it mean concretely? Does it mean that we finish with the pandemic? For government? Does it mean that you have a new recommendation? Does it mean that you are not expecting a new wave in H1N1? So can you a little bit elaborate on that?

**Dr Keiji Fukuda:** When we look at the post-peak period, this is a period in which we consider that the pandemic is still continuing. However, what it also indicates is that this is a transition period where we are moving away from the worst of the pandemic, more towards regular seasonal influenza activity.

Now because it is transition period, I think that countries will be anticipating, are there new recommendations, are different steps that they should be taking. And this is one of the discussions that we will be having with the Emergency Committee. And to get some of the guidance on what recommendations they would expect, to be made. But at the same time, WHO is already going ahead to look at the kinds of recommendations which might be made for countries at that period. And so these are some of the concrete issues which will be discussed. And the Emergency Committee itself will base its guidance, based on the available scientific information. So they will take a look at that information, and look at the overall picture worldwide, and then provide their guidance to WHO on what they think the situation is. And then if they have additional guidance to WHO about steps should be taken. We will take that guidance in also. So I hope that clarifies.  Thank you.

**Gregory Hartl:** Last question from Robert Louis, of MedScape Medical News, please go ahead.

**Robert Louis, MedScape Medical News:**  Well, thank you for taking my call Dr Fukuda, I have two questions. One: can you describe a little more of the outbreak in Senegal, when the outbreak or the community transmission occurred, and also how many deaths so far in that country? And second, can you describe the state of vaccine redistribution that is some countries apparently are not using the supply that they occurred. There have been efforts to redistribute it to other countries where it is in shorter supply. Do you have any details on that?

**Dr Keiji Fukuda:** Thank you for the question. I think that I do not have dates on the first community transmission in Senegal. These are reports which have been received recently by WHO, but I do not have specific dates on hand right now. So I think that if you can be in contact with the media people, afterwards, we can get you some specific information we can provide at this time.

In terms of the second effort and the vaccine distribution, yes, we are in a situation in the world right now where there are countries which have vaccines available and there are countries which would like to have vaccines, but do not have access to them. And so in this situation, there are a couple of large activities going on.

One of them is that, WHO has been working with a number of countries, both donor countries who have vaccines to donate, as well as the commercial sector, from some of the companies who are also donating vaccines, as well as donations of things such as syringes and ancillary supplies, and trying to facilitate the movement of those donated vaccines and ancillary supplies to the countries that do not have them. And in addition, there are some countries that are on bilateral basis, have been in discussion about moving some of their vaccines from their countries to other countries. And so for WHO the first shipment of the donated vaccines began in January, and so we will be continuing with this effort. Overall, we have seen that about 95 countries have expressed interest for receiving these vaccines. And that about, am not quite sure of the exact numbers, but I think of about 35 or 40 countries have had detailed discussions with WHO and provided all of the details needed to move the vaccines to those countries. So we are hopeful that these vaccines will be moving out quickly over the next days and weeks, and we can get out as much as possible. Thank you.

**Gregory Hartl**: thank you very much, Dr Fukuda. We are going to take one last question, and just a second but to follow on from Mr Louis's question, we have 14 reported cases from Senegal. Apparently, all of them are mild. There have been no deaths reported in Senegal. We have few other details on those cases. For more information, please contact us in the media office at the following media email address: flumedia@who.int.

Thank you very much. Now to the last question, from SkyNews.

**SkyNews:** My question is that Dr Wodarg from the Council of Europe has made some serious allegations against the WHO. WHO in response has said that it welcomed the criticism and has said that there will be an investigation into the possibility that WHO has been influenced by the pharmaceutical interest. I want to know Dr Fukuda, to what state is this investigation right now?

**Dr Keiji Fukuda:** Ok good question. Let me clarify this situation. Yes, we welcome criticism and input from any party. I think that without such observations, we are never going to get better in how we respond to events. And this is one of the crucial things for this organization, and I think for all responsible organizations, to figure out how we do better with the next outbreak, next large disease event, and so on. Now WHO is not conducting an investigation based on any allegations raised by Dr Wodarg. What WHO is doing is initiating a very large assessment of several things related to the response to the pandemic. So under the International Health Regulations (IHR), which outlines a process for conducting an assessment of how well the International Health Regulations themselves worked, in handling, and functioning, over the past few years, what we are going to do is take that same process and also use it to help assess the response to the pandemic. And as part of this response, we are going to be looking at a couple of key things.

One of them is that, we will be looking at the overall international response. How effective was it? What things worked, and what things did not work. So well, in what things can be done to make things better. We will also be looking specifically, or asking the review committee to specifically to look into at how WHO performed. How well was it, how well did it do in terms of preparedness, how well did it do in terms of response? How appropriate were its actions? And so these will cover things like communications. These will consider activities such as interactions with this expert groups and advice, and it will also consider how appropriate and effective the actions were in terms of things such as different recommendations, different actions related to vaccines and so on. So it will really be quite a broad assessment. But I want to point out that the purpose of this assessment. The purpose of this assessment is really to find out what is that we should learn, so called lessons learned, and that how do we take that and apply them, and how do we strengthen both this organization, but the entire international response in handling future outbreaks and future large disease events. Because we expect to see additional pandemics in the future, we expect to see future global public health situations which require a large coordinated response, and are driving question is what we do, to do it better the next time. So again, let me clarify, this is not been done in terms of responding to any allegations, or by any individual, but it is really being done to identify how we are going to strengthen the international response to these kinds of issues in the future.  Thank you.

**Gregory Hartl:** Dr Fukuda, thank you very much. And that has been our virtual press briefing for today, Thursday, 11 February. The audio file from this briefing will be available very shortly on www.who.int, and there will be a written transcript up later. Thank you very much, and have a good day.

# Transcript of virtual press conference with Dr Keiji Fukuda, Special Adviser to the Director-General on Pandemic Influenza

18 February 2010

**Gregory Hartl:** Good afternoon. It is just gone one o'clock in Geneva. We are coming to you from the WHO in Geneva, and it is the 18th of February. Welcome to our weekly virtual press briefing. With us is Dr Keiji Fukuda, the Special Adviser to the Director-General for Pandemic Influenza, and just before I hand over to Dr Fukuda, could I remind you please that you will find shortly after this press briefing, an audio file and a written transcript of this briefing on the WHO website, that is www.who.int. Callers who would like to ask a question, please dial 01 on the keypad to get into the queue and now, we will now hand over to Dr Fukuda. Thank you.

**Dr Fukuda:** Hello everybody, and welcome to this virtual press conference from WHO. As usual, let me briefly update you on the current disease activity and then talk about some more recent issues which I think will be of interest.

In terms of the epidemiologic activity, it is very similar to what we reported last week, in which we have seen the highest levels of activities occurring in parts of Eastern Europe, some parts of Northern Africa and parts of Asia. And then similarly, as I reported last week, we first started seeing reports of community-level transmission in Western Africa, in Senegal.

And this week, we continue to see reports of community transmission but also in Mauritania. So we continue to see activity in Western Africa.

Now yesterday, we concluded a four-day meeting which was to look at vaccine strains for influenza vaccine for the 2010 and 2011 season. And we just concluded the public announcement for these strains a little while ago. And so what I would like to do is both review the process a little bit, and then go over the recommendations and the implications of the recommendations.

WHO routinely holds a consultation twice a year, with advisers from WHO collaborating centers and a group of national regulatory authorities to recommend influenza vaccines strains to be used in the northern hemisphere vaccine, and then in a separate meeting for the southern hemisphere.

It is the advisers from these organizations who provide formal advice to WHO on which strains should go into the vaccines. But also at the meeting, there are a number of observers, and these are generally directors from national influenza centers as well as representatives of other technical organizations who come and sometimes provide input and joining in the discussions. However, the observers themselves do not provided the formal input to WHO.

I do want to point out that there are no representatives from industry who partake either as observers or as advisers in these meetings.

Now these consultations which are held twice a year, built upon a series of telephone conferences and other consultations which take place, building up to the face-to-face meeting. And in these consultations which take place before in the meeting as well as this meeting, the scientists who are there go over a large amount of data, and a variety of data. They go over analysis of the viruses, but they also review what the epidemiological picture is and what the clinical impact of these viruses are. And all of this information is taken together to help make recommendations to WHO about what should go into the influenza vaccine.

Now following the recommendation, we hold a public meeting at which anybody who wishes to come may attend. So this public meeting just concluded about 30 minutes ago. And typically at the public session, we often have representatives of industry, representatives from media, and then as well as other interested parties, in understanding what is the most recent picture about the influenza viruses and why, what is the basis for the recommendations that are made.

At the public meeting, we release the information about the formal recommendations and so this goes to all vaccine manufacturers at the same time and the report is put on the web. So it can be seen by anybody. And this is done as soon as the recommendations are made and during the meeting itself.

Also at the meeting, this offers a time for representatives from industry as well as other people to ask questions of the advisers providing the advice. And frequently there is back and forth asking some questions about different aspects of the decision making and the discussions.

Now this year's consultation for the northern hemisphere vaccine, and this was a meeting again to decide what should go into the vaccine for this coming fall and winter in the northern hemisphere. The meeting took four days, and the discussions went very well. The bottom line for the discussions were that we are recommending that the pandemic influenza H1N1 virus go into vaccine for the coming fall and winter in the northern hemisphere. And the consultation is also recommending that there will be a representative H3N2 virus and a B virus. And so these are three viruses being recommended for the coming vaccine.

Now the specific recommendations themselves can be seen on the web, and it is a quite technical group of names, but one of them is A California virus, which is the pandemic virus. The second one is an A Perth virus which is the influenza A H3N2 virus. And then the third virus is the B Brisbane virus which is the third component.

Now this is a very technical discussion and sometimes the information is hard to understand. So let me try to put the discussions and recommendations in a little perspective and try to make it easier to understand.

In essence, in the discussions, what the scientists said was that in the past year, the overwhelming number of influenza viruses that were isolated around the world were the pandemic H1N1 virus. The experts believe based on this information that these viruses will continue to be one of the dominant viruses in wide circulation in the coming fall and winter season in the northern hemisphere. And this is why they are recommending that this virus be put into vaccines for the fall and winter times.

At the same time they looked at the data and they said that the older H1 viruses, the seasonal H1N1 viruses were found very infrequently. And again based on that information, they believe that the seasonal viruses, even if they persist, will not pose a major or significant public health risk to people. And so that virus was not recommended to go into the upcoming vaccine.

The scientist also noted that the seasonal H3N2 viruses and the B viruses were isolated at a much lower rate than the pandemic viruses. However, they were persistent through the year and, in fact, in some countries we are seeing an increase of activity of the H3N2 and B viruses. And so based on this, the scientist concluded that these viruses will continue to pose a significant public health risk to people. And so they recommended that these viruses go into vaccine for the coming year.

Now based on this, let me anticipate one major question which is, does this recommendation or putting the pandemic virus in the vaccine, mean that the pandemic is over? And so let me be very clear. The recommendation to put the pandemic virus into the vaccine for the fall and winter is really a separate issue from whether the pandemic is over. So no, this recommendation does not indicate that the pandemic is over. And the replacement of the seasonal H1N1 virus by the pandemic virus also does not signal that the pandemic is over. Again to underscore this point, the recommendation to put the pandemic virus in the upcoming vaccine really means that this has been a dominant virus. And it is expected that it will continue to be a significant virus, circulating around the world as we head into the winter or the coming winter in 2010 and 2011.

So to underscore this main point and circle back to it, at this point we have to say that the pandemic is not over. However, as I discussed last week and as many of you are aware, WHO will be convening the Emergency Committee under the International Health Regulations (IHR) and this will take place next Tuesday. And this committee will be meeting both to review the overall epidemiologic and virologic situation, and to provide some guidance to WHO as to whether we can consider ourselves in the so-called post-peak period. The post-peak period as indicated in the guidance which was provided to countries before the pandemic occurred, is a transition period in which we continue to expect to see pandemic activity occur at different levels in different parts of the world. But we hope that the worst is behind us and that the overall trend will be going down. So again the post-peak period means that we continue to be in a pandemic. However, we hope that we are transitioning down to a more normal period.

Now, I think that as we begin to transition, one of the important points which I hope is very clear is that we can still expect to see significant levels of activity or perhaps outbreaks occurring in different countries. And here I think that the first report of community transmission occurring in places such as Senegal and Mauritania, is a very good reminder that what we are seeing in some parts of the world, for example Europe or north America, is not necessarily what we will be seeing in other parts of the world at the same time. We really expect that there will be different levels of activity in different parts of the world.

So at this point, WHO considers vaccination against the pandemic virus to be very important. We continue to see this virus in wide circulation. We continue to see that there are a number of people who are at risk for developing severe complications from infections by the pandemic virus. And that the vaccine can offer good protection for these people.

So to remind everybody again that there are certain groups, for example pregnant women, younger people, and especially younger people with chronic medical conditions who are at higher risk than other people for developing severe complications from infections by this virus.

So to summarize here, let me point out that the ending of a pandemic is not an on and off phenomenon, we really expected it to be more of a tailing off phenomenon in which there will be a transition back to a more normal period but it is not an on and off phenomenon, it does not happen overnight. The inclusion of the H1N1 pandemic virus in the influenza vaccine does not signal that the pandemic is over rather the right interpretation of it is to say that this virus is expected to be a significant threat to people as we go into next year's fall and winter period and therefore protecting people against it in the vaccine is the basis for that decision.

Another point is that WHO continues to recommend vaccination for people and especially for certain groups of people such as healthcare workers and people at higher risk for developing complications such as pregnant women, and people with chronic medical conditions.

Finally, next week we will be holding discussions with the Emergency Committee as to whether we may be in a post peak period and if such a determination is made we would still like to point out that WHO will be working closely with countries to make recommendations and take all possible steps to help protect people against this pandemic infection. With that let's go on to questions and I am happy to entertain whatever you have to ask. Thank you.

**G. Hartl**: Before we go to questions if there are any, I would invite journalists to dial 01 on the keypad if they would like to ask a question and to remind journalists that shortly after the end of the press conference an audio file will be available on the WHO website, www.who.int and that the later in the day we will also have a written transcript. So the first question is from Bloomberg in London, go ahead please:

**Bloomberg**: Do you anticipate that vaccine manufacturers will continue to manufacture separate pandemic vaccine for very long or to stop production of it. Is there still a need for it now that H1N1 is included in the seasonal flu vaccine and can people who are already vaccinated against H1N1 also get the seasonal flu vaccine containing H1N1 in 2010 with no consequences?

**Dr Fukuda**: These are very good questions. I think that the final decisions about what kind of influenza vaccines should be made, whether we should continue to have monovalent vaccine or just a trivalent vaccine that is vaccines containing the three viruses or whether there should be a combination of these are decided by countries and in meetings held with the national regulatory authorities.

In addition, however, in April WHO meets with its SAGE Committee - the Strategic Advisory Group of Experts - who provide immunization advice. They will also discuss whether we should be making one vaccine or the other or both types of vaccines. I think that the most important part of this question is that it is possible that as we eventually transition back to a more seasonal picture around the world that this pandemic virus may continue to pose some risk for groups which often do not get vaccinated. That is, younger people and oftentimes women who are pregnant and so I think that one of the questions that has to get looked at is whether there will be additional need for monovalent vaccine in some countries to help provide protection to groups that do not often get vaccinated against seasonal influenza so I think that this discussion is not completed yet and we will see what the recommendations are coming out of some of the countries as well as SAGE.

Now in terms of the question on whether getting vaccinated with seasonal trivalent vaccine in the fall time if you have already gotten vaccinated with pandemic vaccine poses any unusual risk or any danger. With the current pandemic vaccine, we have now seen that over 200 million have gotten vaccinated with this vaccine. The monitoring for side effects and adverse effects have been unusually high and the reporting and the monitoring and the assessing of the safety events, any reported safety events, has been unusually high and what we have seen is that there have been no unusual reports of unexpected adverse effects or side effects and in general the safety profile of these vaccines has been excellent, comparable to seasonal vaccines or perhaps even a little bit better. Right now we have no evidence to suggest or no reason to suspect that getting vaccinated with the trivalent seasonal vaccine - even if you have been vaccinated earlier with the pandemic vaccine - should cause any problems at all. Thank you.

**G. Hartl**: Thank you very much. The next question is from Maria Cheng, Associated Press London. Go ahead Maria please.

**Maria Cheng, Associated Press London**: Hi, thanks for taking my question. I wanted to ask if WHO has worked out the criteria for determining when the pandemic is over. Dr Fukuda, you said that it would not be an on and off phenomenon, I'm just wondering if you have identified what markers you will be looking for or if that is something that the Emergency Committee will be discussing next week.

**Dr Fukuda**: Thank you for this question. Maria, when we look at the guidance which was provided to countries in the 2009 Preparedness Guidelines, what those Guidelines discuss is the post peak period which is the transition period as well as the post-pandemic period which signifies when we have a quite good expectation that we are really getting close to the normal period and out of the pandemic period. I think that similar to the discussions on the post peak period we will be meeting with the Emergency Committee and asking for their advice and also using the criteria provide in the Guidelines as to whether we are in a post-pandemic period. I think that these discussions will take place in the future. Unless the Emergency Committee brings this up we are expecting to hear more from them about the post peak period but I anticipate that in the future of course we will be taking about the post-pandemic period. Thank you.

**G. Hartl**: Thank you. Before we move to the next question, can I remind journalists again that if you wish to ask a question, dial 01 on your keypad. Next question is from Miriam Falco of CNN - go ahead please.

No reply

**G. Hartl**: Sorry, we will have to go to another questioner. Richard Knox from NPR, go ahead please.

**R. Knox**: Thank you very much. I wonder if you could talk a little bit about the practical effect of declaring a post peak period or phase would be - what happens if that is decided?

**Dr Fukuda**: The practical effect of indicating that we are in a post peak period is really to give a broad signal to the world that even though we may continue to see pandemic activity that we expect that we are transitioning more towards a normal level. I think this gives a heads up to countries about needing to plan ahead and to take a look at any measures that they are taking that they have in effect and whether they want to begin changing any of those measures. It really will be a good signal for countries as to planning for when they are going to transition back into a post-pandemic period. That's probably the most practical effect but also it will push us all to look at what different recommendations may be needed, whether there are any different activities which are needed to put in place as we transition back to a post-pandemic period. So that is probably the most practical effect of such an indication. Thank you.

**G. Hartl**: Thank you very much. The next question comes from Asashi Shimbun. And before we go to the actual question, again journalists who wish to ask a question dial 01 on their keypad. Over to you Asashi Shimbun please.

**AS**: Hello, thank you very much for taking my question. I am wondering this WHO recommendation composition for influenza vaccine means that pandemic influenza has become one of the seasonal influenzas?

**Dr Fukuda**: I think the best interpretation again is - or the most helpful way to think about this is to keep the recommendation for the vaccines separate from the question of whether we are in a pandemic or not. If we look at the information which we have on the viruses and the disease patterns in the world, this information here tells us that we should expect that the pandemic H1N1 virus is still going to be widely circulating in the fall time, in the winter time, and that's why we ought to put it into the vaccines.

On a separate note, what we will be doing is taking a look at the disease patterns around the world, trying to monitor how the levels are going and trying to determine whether there is any information suggesting that we are really trending downwards and we should not be expecting any major upsurges in activity. Then on the basis of that kind of analysis decide when we should be calling for or declaring a non-pandemic period. So the vaccine decisions does not tell us whether we are in a pandemic or not, they really give us guidance on how to protect people and then separately we will be looking at all available epidemiologic information and viral information to decide whether we are moving out of the pandemic or not. Thank you.

**G. Hartl**: Thank you very much. Richard Knox has a follow-up question, if we can go to Mr. Knox please.

**Richard Knox**: I didn't but I can probably think of one. I think you mentioned this before but I would like to be little bit clearer - do you expect at this point that the same people who were most at risk for infections with the pandemic virus in the past 10 months that is to say a younger demographic than we see in normal flu seasons will be at risk in the next fall and winter and therefore that that group should be targeted for vaccination and perhaps older people not.

**Dr Fukuda**: That is a very interesting and I think very difficult question. I think that it would be surprising if we see a very abrupt change in who is at risk from this virus. I think that even as the virus begins to mutate and change over time, it has established to some extent who is at risk for developing severe complications from it. Now, one of the difficult parts of your question is that the people who get very sick from this pandemic virus tend to get very sick in a way which is different from some of the other influenza viruses, the other seasonal influenza viruses because the pandemic virus more often directly infects the cells in the lungs and people often develop direct viral pneumonia which is a very severe complication and which is something we see much less often than with seasonal influenza viruses.

So I think that one of the important scientific questions and one of the things that we will be monitoring very closely is whether we see changes in the clinical pattern, how this virus causes severe disease in people, and whether they are the same groups of people we are seeing now continue to be at higher risk than other people and whether we continue to see lower rates of infection in older people. Now the other important part of this is that in general it is true that older people get infected less often than younger people. This is pretty clear from around the world but what has also become clear is that when older people get infected they turn out to be very vulnerable to infection so they probably have the highest death rates even though they get infected less often. This is a little bit complicated but these are some of the patterns that we are now seeing emerging. To answer your question, I think it is very difficult to say whether we will continue to see these same clinical patterns but it would be surprising to see them change abruptly very quickly but we will monitor. Thank you.

**G. Hartl**: We are coming back and Dr Fukuda who is going to clarify one point and then we will go to the next question.

**Dr Fukuda:** I am sorry, if I miss-spoke, it was just pointed out to me that when we are talking about pandemic H1N1 viruses, these viruses cause viral pneumonia more often than seasonal viruses. I think I may have said that backwards, but the pandemic influenza viruses which cause viral pneumonia much more often, and this is one of the crucial differences between this pandemic virus and the other seasonal viruses that we have seen. Thank you.

**G. Hartl**: Thank you Dr Fukuda. So now to the next question, Jonathan Lynn from Reuters, go ahead please.

**Jonathan Lynn:** Hello, am trying to save my question. This is about the stocks of the H1N1 pandemic vaccines that are already there. I know you already touched on this. But could you clarify whether it's both governments and manufacturers who can really use those existing stocks for the new seasonal vaccine or not?

**Dr Fukuda:** this is a very important question. When we look at the monovalent pandemic vaccine, which has been made, some of these have already been put in syringes and in vials. And those vaccines, the vaccines which are put in those kinds of forms, will not be re-used, or cannot be re-used. However, manufacturers are also making the H1N1 vaccines component, and so this vaccine in that form can potentially be used for the vaccine for the upcoming year. And so I think it is important to know that there is a difference of whether these vaccines have already been put into final form, in which case they would not be possible to put them into next year's vaccines. Whether they are still being manufactured in large bulk form, in which case they would be theoretically possible to put them back into vaccine for the coming year. So it depends on what kind of form we are talking about. Thank you.

**G. Hartl:** Thank you very much. So one last reminder to any journalist who would like to ask a question, please dial 01 and before that, we will go over to Robert Lowes, from MedScape Medical News. Please go ahead.

**Robert Lowes:** Hello Dr. Fukuda, thank you for taking my call. I have two questions.

One, I want to clarify something. I understand that this WHO advisory group is not specifically recommending that these viruses strains or three virus strains should go into a trivalent vaccine. Is that correct that you are not recommending a trivalent vaccine which includes the pandemic H1N1?

And second, if that is the case, is it a good idea for countries to adopt a trivalent vaccine with this pandemic virus. Would that be a good idea? Thank you.

**Dr Fukuda:** Sure. Okay, good question.

Let me provide this clarification. Yes, at this consultation here, we do not ask the advisers to advise on whether there should be monovalent vaccine or whether there should be trivalent vaccine. What we asked them to do is that based on the available scientific information, what viruses should be covered in influenza vaccine. And then in essence, there is a two-step process. After these recommendations are made, there are additional discussions which take place with advisory groups often to the national regulatory authorities or regional regulatory authorities, discussing whether they should have a trivalent vaccine or whether they should have a monovalent vaccine and so on. So again, there really is a multiple step process with different groups giving their input on different type of questions.

As to whether trivalent vaccine makes sense, I think that, yes, for many countries, I think that the answer is that a trivalent vaccine would make sense. There are countries which use a lot of seasonal influenza vaccine. And the seasonal influenza vaccine containing the pandemic influenza virus plus the H3 and the B virus could be very useful, and people would just vaccinated per routine. There are other countries for which other formulations may make more sense or a combination or formulation may make sense. So I think these discussions have to be decided more at the national level. Thank you.

**G. Hartl:** Dr Fukuda, thank you very much. And to you listening, that's been our virtual press briefing today, 18 February, and one last reminder, the audio file from this virtual press briefing will be up on the WHO website, at www.who.int, and it will be up there shortly. There will be a transcript up later in the day, and just to let you know that next week, our virtual press briefing by Dr Fukuda, will happen on the Wednesday, not Thursday, so that will be Wednesday, at 11 o'clock in the morning Geneva time, 24 February. Thank you very much until next week. Good bye!

# Transcript of virtual press conference with Dr Keiji Fukuda, Special Adviser to the Director-General on Pandemic Influenza

### 24 February 2010

**Gregory Hartl:** Good morning. It is 11 o'clock here in Geneva and welcome to the World Health Organization's virtual press briefing. Today Dr Keiji Fukuda Special Adviser to the Director-General for Pandemic Influenza will be speaking about the deliberations and outcome of the Emergency Committee Meeting which occurred yesterday so I would first like to remind you that shortly after this briefing is over the audio file will be up on the WHO website and later in the day, that will be followed by a written transcript and now I would like to turn over to Dr Fukuda.

**Dr Fukuda:** Thank you, Gregory. Again thank you everybody for joining this virtual press conference. What I will do today is discuss the meeting of the International Health Regulations Emergency Committee which met yesterday and had its 7th discussion since the start of the pandemic.

This meeting was held as a teleconference meeting and the discussions were quite interesting and I think, important. Now the Emergency Committee was convened for two main purposes. The first one was to provide the Director-General with the Emergency Committee's views on the status of the pandemic; where we stand right now. The second thing was the Committee was asked to address and review the current temporary recommendations which are in place. These temporary recommendations are reviewed as a matter of course every three months as part of the International Health Regulations.

Yesterday's discussion lasted about 2 hours and it was really a quite in depth discussion about the current situation. Based on the evidence that was presented in that discussion and based on the subsequent discussions and the views of the Emergency Committee the Director-General decided that it was appropriate not to make any changes in the current pandemic phases right now and that she would reconvene the Emergency Committee some time in the next several weeks to again review the pandemic situation.

Let me give you some insight into the Emergency Committee's deliberations. Now the discussions that were held among the members were quite in depth and they went over the epidemiological situation in some detail and they also raised a number of other issues and concerns among the Emergency Committee. So in terms of the epidemiology the Emergency Committee noted that pandemic activity is at different places in different parts of the world. So for example they noted that pandemic activity is clearly declining or is low in many parts of the world, in many countries. So for example, over the past few weeks we have talked about how activity is low in places such as North America, in Western Europe and in a number of other places in the world. But we have also noted that there has been some ongoing activity going on in other parts of the world. Such as Eastern Europe, parts of Eastern Europe, parts of Central Asia and so on.

Then more recently the Committee also noted that there are increasing reports of pandemic activity occurring in Western Africa. So in the past few weeks we have reviewed the situation where we are seeing the first reports of community activity occurring in countries such as Senegal and Mauritania.

Now in terms of some other concerns that were raised by the Emergency Committee. One, they noted that the Southern Hemisphere is going to be entering its winter months and this is a period of time in which increased influenza activity should be anticipated including pandemic activity. A second point is that we noted that in some countries there had been two significant waves of activities whereas in other countries there had been only one wave of activity which has occurred so far.

Then finally they had some concern that any actions should not undermine any of the control actions being taken place by different countries and so nothing that the Emergency Committee should advise on, should really harm the efforts of countries to try to deal with the influenza activity. So on this basis the Emergency Committee provided its views to the Director-General that it was really too early to conclude that the pandemic was in a post peak period in many countries and that the Emergency Committee should come back and revisit the epidemiological situation in the next several weeks when there is more information to be looked at.

Now let me also provide some other observations about this discussion. I think that the discussion really highlighted a lot of the real world complexities of dealing with a large event like a pandemic. They underscored on the one hand, the need for pandemic plans, these kinds of plans are essential for helping countries to be prepared and to coordinate their preparations and actions in dealing with something like the pandemic.

When we look at the current plans these really reflect the ongoing work by scientists since really the late 1990s to try to provide updated guidance and based on an extensive amount of real world experience plus scientific knowledge. They also noted that the current plans - the current pandemic plans - which came out in 2009 also reflect concern over the more severe kinds of influenza pandemics and this has really been driven by the fact that we have been dealing with avian influenza, avian H5 and H1 influenza for a number of years and it remains a concern for countries.

But this discussion also highlighted the need for everyone to keep their eyes open to reality and to see what is going on and not just to look at plans. And so in the current situation we really see that this pandemic is on the less severe end of severity. Again we don't really know what the final impact is and we won't know what it is until a year or two after the pandemic is over but it appears to be on the less severe side of the spectrum of pandemics that we have seen in the 20th century. It's also clear that in the current situation countries are in different situations in terms of disease and epidemiology. What is being seen in one country is not necessarily what is being seen in other countries in other parts of the world. Then finally, I think these discussions highlighted that countries are also in different places in terms of their efforts to mount control programmes and to deal with the pandemic and so, for example, in some countries we have seen that vaccination has been going on now for some months whereas in other countries similar sorts of efforts have really yet to get started.

Then I think the discussions also underscored one reality that we always deal with in dealing with an event like the pandemic which is that there are fundamental limitations in terms of knowing what course the pandemic is going to take. We are always unsure whether there are going to be significant changes in the future but we know that that can happen and if they are going to happen we don't know what they might be or when they may occur. This is really something that we have always had to deal with.

So if you look at this and you say what does this mean?  I think it really boils down to a couple of points.  On the one hand it's clear that we need pandemic plans and guidance because it's really essential for helping countries to plan their activities and to deal with the situation.

On the other hand these actions really have to be flexible.  We have to keep our eyes open to reality to see what is going on, on the ground and then adjust our plans and actions as dictated by that reality.  So we have to be flexible.  So this is really a lot to ask of groups like the Emergency Committee and also of health authorities but really this is what they must do.  They have to balance these two things.

So in closing before I move on to questions let me just summarize. WHO is not calling for any changes to pandemic phases right now.  WHO is also not making any changes in its recommended actions at this time and that the Emergency Committee will be convened some time in the future, within the next several weeks to review the situation again and then we will come back and look at the pandemic situation and see if there are any changes in phases or recommendations at that time.  So let me stop here and then we will turn it over to questions as normal.  Thank you.

**Gregory Hartl:** Dr Fukuda thank you very much for those introductory remarks.  Before we move over to questions may I remind journalists please that if you wish to ask a question please dial 01 on your key pad.  So the first question is from Frank Jordan of Associated Press in Geneva.  Go ahead please Frank.

**Frank Jordans. Associated Press:** Good morning Dr Fukuda.  The way I understand it is that the Committee found the situation was more volatile in the Southern Hemisphere and more stable in the Northern Hemisphere.  Could you tell me if they made any recommendations specific to either of those about what countries can and should do at this stage now?

**Dr Fukuda:** Thanks Frank.  I think it's probably more fair to say that they didn't find the situation more volatile in the Southern Hemisphere but what they noted is that with the Southern Hemisphere's winter months coming up that this is traditionally the time when we expect to see higher levels of activity and that they were noting that, and they were saying that it was possible that we would be seeing things in the Southern Hemisphere which could be much higher than would be expected with seasonal influenza. So I think it was really more a note of caution about what the future could bring in the Southern Hemisphere. And so at this time they did not make any recommendations which were specific either to the Southern or Northern Hemisphere and make any distinctions here. Thank you.

**Gregory Hartl:** Thank you. The next question is from Jamil Chade - you're in Geneva. Go ahead Jamil.

**Jamil Chade:** Thank you Gregory. Mr Fukuda you mention the vaccination issue. Brazil will start its vaccination and campaign next week. I understand that what you said if you would make any changes at this point it would basically change the behaviour of people going to the centres to get vaccinated, but the fact is that we have seen in Europe that the vaccination process was very weak. So my question is, is it really necessary, this measure, at this point of time, in Brazil?

**Dr Fukuda:** good question.

Right now the situation with the pandemic virus can be summarized this way.

We have seen that this has been by far the dominant virus around the world over the past year, and all indications are that this virus will be around for quite a long time.

And secondly, we have seen that this virus has really caused its more most severe impacts in certain groups. And so for example, we have seen, as I mentioned in the past, that pregnant women and younger people are more likely to develop severe disease.

Thirdly, we have now seen that over 300 million people, an estimated 300 million people or more, have now been vaccinated against pandemic influenza and that the safety record of the vaccine has been excellent. We have not seen any unusual safety events occur.

And then finally, we are now becoming to see the first reports coming out in which the effectiveness of the vaccine is about seven to seventy-five percent, which is quite high, that we have a vaccine which can affectively protect against this infection. So when we look at all of that information we see that people in Brazil, as in other countries, many of them are still very susceptible to the infection. Some of them, If they are infected are likely to develop severe consequences from the infection. And that if  vaccine is available, WHO definitely recommends that vaccination is a very good way to protect people against this infection. So we are not changing any of our recommendations for influenza vaccination but continue to endorse them. Thank you.

**Gregory Hartl:** Thank you very much Dr Fukuda. Before we move to the next question, I would like to remind journalists that if they have a question, they should dial 01 on their keypad to get into the queue. So the next question is from Andrea at Bloomberg, go ahead please.

**Andrea, Bloomberg:** Hi Dr Fukuda, could you just give us an update on the number of people estimated to have died, who have been laboratory confirmed cases, and also did the emergency committee decided not to change its recommendations because it was concerned that countries might stand down on the control measures they were taking?

**Dr Fukuda:** OK, thank you for the question.

I believe that the current estimates of laboratory confirmed deaths are something over 16,000. I do not have the exact numbers here, but we can provided them to you if contact the media people here.

Now in terms of the, what really drove the discussions at the emergency committee, I think the most important point that they noted was that, they saw that the disease situation was different in different parts of the world. You know, there was lot of discussion of what was being seen in one country, is not the same as what was being seen in another country, and that given the situation that, for example, in West Africa, we are not just beginning to see increases and entry of pandemic influenza into that part of the world, and that Southern Hemisphere is getting ready to go into the winter months. These are really the dominating concerns of the committee. And this is why they said, you know, it is really probably too early for us to advice or give views on whether we are in a  post-peak period or not. But in going through those discussions, they were very broad and they went into in-depth on a lot of issues. They also noted that they did not want to undermine control and actions being taken in other countries. But the dominating consideration was what the epidemiological picture in the world. Thank you.

**Gregory Hartl:** Before we move to the next question, I would like to remind journalists that if they have follow-up, they can contact us at flumedia@who.int, and our dedicated phone line for pandemic influenza is +41 22 791 5000. So if any other journalist have a question, can we remind you again, pleas to dial 01 on your keypad, to get into the queue, and until we have any more questions, I will take this opportunity  again to remind you that the audio transcript of this briefing will be up on the WHO website, which is www.who.int very shortly, after the end of this briefing and the written transcript will be up later in the day.

So now we will move to the next question which is from NHK, go ahead please.

**NHK:** Hello Mr Fukuda, thank you so much for your brief. Just one question about the details of which country is seeing the increase of pandemic, in Africa, is it only 2 countries, Senegal and the other one?

Dr Fukuda: Yes, two countries that we are getting increases in laboratory confirmed infections are Senegal and in Mauritania. I think that we will be working to try to see whether there is additional information from other countries in the area. But these are the countries in which we have the laboratory confirmations. Thank you.

**Gregory Hartl:** Dr Fukuda, thank you very much, and if there are not any further questions in the next minute or so, we will  say goodbye for the day, but I am seeing that there is another question coming through. Can you go ahead please?

Frank Jordan, Associated Press: Yes just a quick follow-up from my only one and also the answers you gave to the other questions. It seems to me like the pandemic recommendations are pretty sort of blunt instruments, if the current situation in Senegal and Mauritania is what is holding up a phase change or recommendation change for the whole or the rest of the world?

**Dr Fukuda:** Thank you! Is that a question or a comment?

**Frank Jordans, Associated Press:** Do you have any comment on that? Is it fair that, you know, the situation one corner of the world is being used to make recommendations to the whole of the rest of the world?

**Dr Fukuda:** Frank, I think that is a very good and difficult question in a certain way.

I think that, If we look at how the world deals with these large global events, I think that some of the recommendations made at the global level certainly are blunt because they are really intended to be relevant and germane to the world. But it is also clear for example, that the situation can vary from region to region or from country to country, but to handle those situation also, you know there are recommendations which of course are made by regional authorities or  made by national authorities. And so the discussions held yesterday really reflected that reality, that in the world we really have a different situation going on. But also remember much of the discussion did revolve around what is going to happen in the next few months, in the Southern Hemisphere. And that based on how we know influenza typically behaves including pandemics, that in the winter months, you can expect to see a kind of activity that you do not see in the summer months. And so all of these went into to the discussions, and one of the things which I drew from that, is that, you know, again, we have to be very mindful, not to try to oversimplify what is going on in the world or oversimplify how we look at what is going on in the world. So I think that it is not simply the fact that we have activity going on in one part of the world, but we have that, and also we some reason to be concerned about what may develop as have of the world goes into its winter months. So, again the discussions are really quite realistic about these things and, point out the difficulties of two rapidly or two oversimplifying what the issues are. So any way, so I hope that that is helpful. Thank you.

**Gregory Hartl:** OK, thank you very much. Before we move to the next question, I can confirm that the latest count that we have of the number of laboratory confirmed deaths, so again, these are laboratory confirmed, is 16,226 deaths, as for this moment, confirmed in the laboratory.

So we will move to one more question, and that will be from Lisa Schnirring, of CIDRAP News, good morning. We know it is very early for you, welcome and over to you and to Keiji.

**Lisa Schnirring, CIDRAP:** Thanks so much for taking the question. I have a two-part question, both relating to the Southern Hemisphere. Am wondering if there is anything that usually happen there this time of the year, the kind of things that you watch for, events like school starting or the weather changing.  Anything that seems to be related to flu getting going there, or anything they might already be seeing that is changed in the last week or two.

The second last of my question is, regarding vaccination in the Southern Hemisphere. Are most of the countries getting the monovalent pandemic vaccine or are they getting seasonal vaccine that has the pandemic strain in it? Thanks so much!

**Dr Fukuda:** Thank you Lisa.

In terms of your first question, probably the most important predictor of when we might see activity pick-up in the Southern Hemisphere is simply what part of the year we are in. As you know with pandemic influenza, we can see activity occur in summer months. This is an atypical seasonality compared to regular influenza. But we also know that for both seasonal influenza and for pandemic influenza, entering into the winter months means that you are entering into the period when you are most likely to see influenza activity occur. So I think that that is really probably the most important thing to know, just where we are in terms of the year. Otherwise, we do not have, you know, we can see activity occur in schools and in communities, but its really the time of the year which is probably the most important marker.

Now in terms of the your second question, monovalent versus trivalent vaccine, for the past year, the vaccine which has been available for the pandemic has been monovalent vaccine, that is a vaccine containing one virus specific to the pandemic virus. Now last year, in September, the health authorities in the Southern Hemisphere went on to decide that the vaccine that they would be recommending for use in the Southern Hemisphere now in the year's winter, would be a trivalent vaccine, containing the pandemic virus plus two seasonal influenza viruses.

And so most of the vaccine that will be available there, will be trivalent vaccine. It may be possible that there will be monovalent vaccine use, but I expect that more of it will be trivalent vaccine in the southern hemisphere. But currently, we are in an interesting period where both vaccine are available. Thank you.

**Gregory Harlt:** Dr Fukuda, thank you very much. The next question is from Jules Carron, of Kyodo News in Geneva, please go ahead.

**Jules Caron, Kyodo News:** Thank you Dr Fukuda. I have two small questions.

First of all, decisions within the emergency committee, how are they taken? Is it a vote? Is it unanimity? And basically, what were the numbers? Were they half one to two, to post-peak and half wanted to stay?

And second is, you said you will be meeting again in a few weeks. You will be meeting in a few weeks to ask yourself the same questions? Is that right?

**Dr Fukuda:** Thank you. The way that the committee works in terms of its discussions is that the committee is run by the chairman, who often goes around and will ask each of the members specifically for their views when a question is raised, and then there will be general discussion. And then the views really come together as a consensus. So in terms of the discussion that were held yesterday, the points that were made about not having enough information at this time, and wanting to revisit the issue was really a consensus decision in which I think it is fair to say that it was the unanimous view of the emergency committee.

Now when the committee is brought back again, and again, I do not have precise timing of this, because this will depend on how the situation evolves around the world. But when the committee comes back together, sometime over the next several weeks, they will again be presented with the situation, the epidemiologic situation, and I expect we will again go into another discussion about where are we in terms of the pandemic situation and are they are ready to provide any views on whether there should be changes in the phases and whether there should be any changes in any recommendations. So I expect that the questions will be similar to what were raised at yesterday's meetings. Thank you.

**Gregory Hartl:** Thank you Dr Fukuda. And now to our last question which is from Lisa Schlein from VOA. Lisa go ahead please.

**Lisa Schlein, Voice of America:** Dr Fukuda, you mentioned that the pandemic is emerging now in Senegal and Mauritania. Now are you concerned that, it might actually blow up and become out of control in the African continent because of the poverty, of the continent, I think that is probably less prepared in terms of vaccinations, and other control measures than countries in the richer part of the world. And what measures are you taking in order to prevent the situation from really becoming, well out of control as I say.

**Dr Fukuda:** Thanks Lisa.

I think that the recent activity which has been reported from Western Africa, one points out that we should not be complacent about where activity may be going on. So for example there have a lot of reports coming out in North America and in western Europe about how activity is low. But what is going on in those parts of the world does not necessarily reflects what is going on in other parts of the world.

Now in terms of Africa specifically, because there a number of chronic conditions, and because the conditions like poverty and sometimes difficulty accessing health services, it is clearly a continent and an area which our concerned about. We always spend time in thinking about how we can best support efforts by health authorities there to protect their populations against a wide variety of disease not just pandemic influenza, but of course other diseases like malaria, tuberculosis, HIV, and so on. So in this particular situation with the pandemic, there had been extensive efforts going on since the start of the pandemic, to provide health authorities there with diagnostic tools, with guidelines on clinical care of patients who are at home, and those kind of efforts And in addition, there has really been a very extensive effort to ask richer countries and vaccine manufacturers to provide vaccines and ancillary supplies, like syringes, so that developing countries, many of them in Africa, are also able to access some of the essential tools like vaccines. So all of these efforts have going on since the start of the pandemic, and we continue with them in  there is no let up in these efforts right now. Thank you.

**Gregory Hartl**: Dr Fukuda, thank you very much, and journalist to you also thank you very much. This has been the WHO virtual press briefing for today, 24th February 2010, and the audio transcript of this briefing will be up shortly on the WHO website, www.who.int., and later in the day, we will have the written transcript up there for you too. So once again thank you very much to all. Good bye!

# Transcript of press briefing at the Palais des Nations, Geneva Dr Keiji Fukuda, Special Adviser to the Director-General on Pandemic Influenza

**29 March 2010**

**Gregory Hartl:** without further ado, we will ask Dr Keiji Fukuda, the special adviser to the Director General for pandemic influenza to make some opening remarks, and then we will open the floor up to questions, thank you very much.

**Dr Fukuda:** bonjour, everybody, good morning. What I will do in the next few minutes is talk a little bit about the review of the pandemic, the process which is coming up and the review of the International Health Regulations, give you a little bit of background about the review process, and then we will throw it open for questions and talk about what you want.

So again, first thanks everybody for taking the time and coming over.

What we will begin this month is a review process to look over the preparedness and the response to the current influenza pandemic. And also review the functioning of the International Health Regulations (IHR), both in relationship to the pandemic but also assess the IHR in terms of other functions not related to the pandemic.

So there are a couple of main goals that we are hoping to get out of this process. The first one is to review how well the world was prepared and how well the world responded to the current pandemic current situation. So we will look at both of those aspects in detail. The second goal that we will get out of this, is to look at functioning of the IHR. I think that all of you know what it is but in essence, the IHR are a large international agreement among the Member States of WHO, about how to handle global public health emergencies and other large events. And so we will see how well this framework functioned during the pandemic, which is the first global test of IHR.

And then, the bottom line for the process is to identify lessons learned. To identify what the world needs to do including countries and organizations like WHO to be better prepared and also to respond to future pandemics and future large scale global public health events. And so this is what we are embarking upon. And so this review process is going to be conducted by an independent group of experts. These are people who are all experts in various aspects of public health and  in science. And the assessment itself will be quite in-depth. We will start off with the meeting in April, but the process itself will continue for some months after the first meeting. So the first meeting is not the entire review itself but its really the start of the review.

We expect that the results of this process are going to be  quite important. I think it will probably be a uniquely broad and in-depth examination of the preparedness and response. And we expect that the findings will be of importance in guiding certainly WHO, but I think that all of the entities involved in responding to global public health emergencies. So it will be a quite, I think useful activity. And again, as I mentioned, the bottom line for doing this, is really to identify what do we need to do to get  better. We know that are things that have to get better, but what are they, and how are we going to improve upon them.

Now the review will be conducted by a so-called review committee. So this is a group of currently considered to be about 29 people. They are people who are going to be drawn from a list of experts who are part of the IHR, so these are experts from around the world who have been identified by countries. They represent a large variety of expertise and backgrounds, both in infectious diseases but in also in non-infectious diseases. So a very large group of experts. And so a group of them will be asked to conduct the assessment.

Now the review committee will operate under the same procedures and rules as do other expert committees of the WHO. So there is set procedures, for example, covering things such as declarations of interests, conflicts of interests, and those sort of things. And the committee will operate under those procedures. The names of the review committee members will be made public by the time we have the first meeting. So currently, we are in the middle of the enrolment procedures and going over looking at various aspects and making logistical details. But we expect to make the names of these people available by the time of the  first meeting.

Now the meeting itself, the first meeting, is going  to be held from the 12th through the 14th of April. So that is coming up fairly shortly.

And I want to talk a little bit about how the committee will do its work.

Now the committee itself is going to set its own methods of work. So the committee itself will decide who it wants to talk to, how it want to get access to various inputs and opinions and reflections. And so for example, they may want to get input from countries. They may want to get input from civil society, they may want to get input from critics, they may want to get input from industry, and the committee itself will decide on how it wants to get input from these different entities. The committee itself will also decide upon who will be the chairman or chair person and the co-chairperson for the process, and so these issues will be decided at the first meeting.

Now we anticipate that there will be a large number of countries that will wa to make its views known to the review committee. And so we anticipate that at the first meeting, countries will have the opportunity to do this, both to provide written inputs but also to be able to voice directly to the committee, what their concerns are, what they think is important, what they hope that the committee will focus on, and those kinds of issues.

As I mentioned, the work of the committee will continue after the first meeting. The first meeting is just when the committee gets together for the first time, decides on how its going to conduct its work over the next several months. Based on the first meeting, the committee will provide a preliminary report of its thoughts to the Director-General, and the Director-General will then provide a preliminary report to the World Health Assembly, coming up in May of 2010.

This is the broad outline of the process. It gives you the rational for why it's been conducted. Again really the bottom line is to find out how we are going to do a better, in terms of preparedness and response. And then broadly speaking, how the review process will be conducted, who will do it, and how it will go forward.

So with that let me stop here, and then we will throw it open for questions. Thank you.

**Gregory Hartl:** Thank you very much. Questions? Frank Jordans, Associated Press.

**Frank Jordans, AP**: Good morning, Dr Fukuda. Since there is been a lot of talk of the issue of conflict of interest, you actually mentioned that, how the rules will apply. Am wondering will any of the people in the committee likely include any of the decision-makers who were part of the process at the time, and what kind of conflicts of interests might arise from that, seeing as that they will essentially be reviewing their own work. And secondly, is WHO not have any kind of review of what happened to so far itself, apart from what the committee might come out with?

**Dr Fukuda:** Sure. Thanks for the questions, Frank.

The committee members are going to be people who represent various areas of expertise. They do not represent countries, they do not represent organizations, but they are being asked to participate on the review committee, because of their experience and expertise in a variety of the areas.

Some of these people will be very well known scientists. Some of these people will be public health people, some of these people will be public health people who were involved in the pandemic response itself. And it will be quite broad. And the reason for this is that we want to mix of people on the review committee who have practical experience as well as theoretical experience. We do not want people who have just theoretical experience but really people who have also their own understanding of how things went. So it will be a mix of a group of people like that.

In terms of your second question, yes, WHO itself has been conducting a review of how well we think that things went and how the management of these kinds of events and how the organization can approach these events better. However, it is important that we separate a WHO review from an independent review of the situation. So within WHO we are really focused on how do we as an organization really performed better, do what we're expected to do. But we are asking the international experts to take a very broad perspective, look at how things went globally, internationally. And as part of that we expect them also to assess how well WHO did. But again from an independent perspective. Thank you.

**Gregory Hartl:** Next question? Lisa Schlein.

**Lisa Schlein**: It so nice to see you in the flesh, Dr Fukuda.

**Dr Fukuda:** Thanks. Happy to be here in the flesh!!

**Lisa Schlein**: I have a couple of questions to ask. One is, are you having the review of independent experts occurring now because you think that the H1N1 pandemic is starting to wind down, and this is an appropriate moment in which to review what has happened and what might happen? And secondly, what are your concerns about, fortunately, we have not been zapped with the 1918 type pandemic, but because the pandemic has been so relatively mild there are lots of skeptical people around the world that it even existed, or that it had the kind of bite that seasonal flu has. So in the process of review, I mean your own thinking, are you not concerned that perhaps, not that you jump the gun, but people may have thought you jumped the gun, and that your credibility is really on line because here you pumped up this great big terrible thing which never really materialized. I mean am glad it did'nt, but that is the situation!

**Dr Fukuda:** Lisa, thanks for the questions. These are good questions.

The timing of the review process, I think reflects a couple of things.

One of them is that we don't know when the pandemic itself is going to be over. However, we are now about a year into the pandemic, I think there is a lot of experience which is been accumulated and in addition, we want to conduct, at least, begin the review process at a time when the memories are fresh, when the experiences are fresh. So for those reasons this seems to be relatively good time to start it.

In addition, as I mentioned, we are conducting the review under the IHR. And one of the things of the IHR called for when they were enacted was that functioning, how well the IHR themselves are going, is reviewed and presented to the World Health Assembly in May of 2010.

So what this review process does is it will take advantage of that call for the review of the IHR, and allow us to use the same process to conduct this review. And so there is a couple of different reasons why we want to conduct it now, or begin the process now.

In terms of the other questions, I think the best way to answer this is that the assessment itself is going to be a very in-depth and very broad review of these kind of questions and we believe that the assessment itself will be a good way to address many of the questions which you're raising now.

It is interesting because there are a number of different questions that can be addressed from the review process. You know for example, it can go ahead over scientific aspects, it can over communications aspects, managements aspects, and so on, but we expect that this process will go into the kind of questions that you have raised here, and we think it is a good way to address it because it will be done by a very credible group of people. So anyway, we hope to see these things addressed directly. Thank you.

**Lisa Schlein:** Excuse me just to follow-up, I know you are not the review committee. But since WHO has been having its own reviews, on-going reviews, what sense do you get about the comments that you get from these skeptics about whether you reacted too quickly, or too strongly? Do you, WHO, shall we say, feel that perhaps, a different tactic should have been used or should be used in the future?

**Dr Fukuda:** Well, it is true, I cannot second-guess what the committee is going to say or find, but one of the things which we do, and which I do personally is I talk with a lot of the representatives from countries around the world. And one of the questions I frequently ask is about how decisions were made and how things went. And these are talking with the people who were responsible for the health in their countries. And again, one of the important distinctions talking with that group of people versus many of the people who are voiced in the media, is that, these are the people who make decisions as they go ahead. These are the ones who have to decide when they have limited amounts of information. And in general, I think there is a good sense that the decisions were made trying to take into account all the information that was available at that time. And so, there are lots of countries who are asking the kind of questions that you are raising, now, themselves. I raise these questions when I talk with our Member States. And again this is one of the things we really want to address. Could we have made decisions better? Could we have considered things in a different way at the time? So again, I don't want, I can't really second-guess what the committee is going to say, and it's for this purpose that the committee has been convened, you know to help address these kinds of questions. But we along with many others are asking the same kinds of questions of ourselves and each other.

**Gregory Hartl:** John Zaracostas

**John Zarocostas**: Yes, good morning Dr Fukuda. Firstly, I would like to ask you, if, given the big public interest and concerns about way this whole thing was handled, at international and national levels. Will the proceedings be open to the public? Will there be a public gallery? That is my first question.

And secondly, if you can give us your interpretation. Was there an amendment or a reinterpretation of the IHR pandemic definition in April, away from morbidity and mortality and more into geographic spread or not? Thank you.

**Dr Fukuda:** Let me address the first question and then the second one.

The meeting of the review committee will be opened to observers from Member States, so all countries in the world will be able to send representatives to observe directly. In addition, the review committee proceedings will be opened to representatives of UN organizations, and also international governmental organizations, the nongovernmental organizations, that are in official relations with WHO. So this group of entities is identified under the, how the experts committees work under, how the IHR conduct these kinds of hearings, or these kinds of proceedings. So this is how this proceeding will be conducted under those procedures.

In terms of your second question, the answer is no. If we go back over the definition of pandemics, again, what we see is that the heart of the definition of pandemics, whether it's for influenza or other diseases, is the emergence and the spread of a disease around the world. The questions about severity have come up because severity is an extremely important part for how decisions makers decide what to do in their countries. You do something differently, when things are mild, you do something differently when things are very severe. But as we have pointed out over and over again, at the start of pandemics, and even if you go into it, it is impossible to predict what is going to happen. We have never been able to say that we know in a few weeks this is where we were going to be, or in a month this is where we were going to be. And so knowing what the severity is of a pandemic is beyond us. We have never made any pretence of being able to predict that and so it was never made a part of the pandemic definition. You know the definition has really, our attempts to get at severity, are on-going but its really not part of whether we are in a pandemic or not. It's really, is their information that we can have on the severity that will guide the actions that should be taken, as part of the pandemic. But they are related but separate issues. But there was no change made in April.

**John Zarocostas:** So just to clarify that there will be no public gallery other than specialized organizations accredited to WHO events. So there will be no press availability to the proceedings. Is that correct?

**Dr Fukuda:** In terms of the press, these are two separate questions. I think that the proceedings of the expert committee, the review committee, will be conducted per normal procedures. As part of the normal procedures the press are not usually invited to experts meetings. However, we are also mindful that this is situation of particular interest. This is much more interesting as normal business and so what we will do is try to work with the media as much as possible to make the information as available as possible. But we are still considering how to do this.

**Gregory Hartl:** Further questions? Can you state your name and agency, please?

**Kaitlin Mara**: Intellectual Property Watch.

I was wondering if this review process is also going to be looking at the pandemic influenza framework that WHO is still trying to finish. And in particular if you are going to look at the way that vaccines were shared with countries that couldn't afford to make them on their own.

**Dr Fukuda:** These are good questions.

I think that, the way I can answer this question is that, the exact scope of the review will be defined by the committee itself. For example, they will address exactly what questions they think they ought to look at and how they are going to do it. And so I cannot answer directly whether they will look at the framework or the attempts to develop a framework on virus sharing and benefit-sharing or not, especially given that there other meetings going on about this. However, I think that, when if we look at the issue of vaccines, vaccines are clearly an important part of the response of the pandemic, so I expect that the committee will be looking at vaccines. But again, I cannot right now tell you how they will frame the questions, or what the scope of that will be.

**Gregory Hartl:** Further questions? Frank?

**Frank:** I'm still not quite clear about how to describe this committee. I mean would you say that they are independent or an outside committee or are they going to be WHO representatives on this committee? And when do you expect the final results? You spoke of preliminary results in May. We will have the final results this year?

**Dr Fukuda:** Frank, let me try to clarify.

First, let me answer your second question. I think that what we are hoping for, although, again the committee itself may say it needs to continue working, but what we are hoping for is that the review committee will be able to finish its work in time for the Director-General to be able to give more final report, for the World Health Assembly of 2011. So that will be next year. So this will give time for the committee work over the next several months and that's when we are hoping the final report will be available.

In terms of how to describe the committee, let me go back a bit to the IHR. I think it will show you how it functions in terms of WHO and how to put this committee in perspective.

The IHR are an agreement among the Member States of WHO so it is a very large umbrella, a very large "chapeau" and the whole purpose of that agreement was to identify how countries can work together to detect events, report events, and act upon them more quickly and more coordinated than in the past. So that is what the IHR in essence are, an agreement among countries on how to do that. As part of that the IHR called for countries to nominate experts who could be there, and who could proved the Director-General with independent advice. So these are experts, again, in a wide variety of areas. And so, this review committee, is a committee that will be drawn from that group of experts. And so they are the ones who are going to determine how they do business. They are the ones who are going to determine how they are going to meet, when they are going to meet, and the scope of their questions. And then the role of WHO in this is that, we will facilitate. If they need help setting up meetings, if they need help for travel, if they will help with getting access to different groups, we will provide that kind of support. But it is a group that will act independently. There are no WHO staff members who are part of it. They are all independent to WHO, and then their findings that they present to the Director-General will be their findings. They will not be WHO's findings.

**Jonathan Lynn, Reuters**: Dr Fukuda, who will draw the members of the review committee from this pool of experts? Will that be the WHO, or the members states, or somebody else?

**Dr Fukuda:** So typically when we pool together a committee like this, one of the things that we aim for is to have a broad geographic representation, so that there are people from all over the world and then we try to make it as balanced as possible in terms of gender balance. And then we also try to make sure that areas of relevant expertise are represented there. So, in order to do this, what we do is we ask the regional offices of WHO to work with Members States in their area. So there's a kind of a discussion in the regions which goes on, and based on that, we come up with people who will be nominated to be on the committee.

And then what we do is go to the people who have been nominated themselves to ask them if they are available and so on, and then based on those kind of discussions, and then asking them to provide declarations of interests and vetting it, then we come up with final group of people.

**Takuya Arai:** Hello Dr Fukuda. From what I understand from your answers to the previous questions, I think it's unlikely to happen that the committee will discuss the possible change of definition of pandemic, in terms of severity, I think. My question is, will the committee discuss other part of possible change of pandemic alert level system itself? I mean the whole system and especially for the geographical spread of the disease.

My second is not always relevant to this review process, but if you have any plans to have the next emergency committee meeting, could you let us know? Thank you.

**Dr Fukuda:** Let me address the first issue first.

Actually, I believe that the committee is going to identify what issues were important to countries and to everybody, I think that the phases, the definitions of phases, the role of severity, I think that these are critical issues. And so again, I cannot tell you what the committee is going to decide to do. That is their responsibility. However, these were clearly important issues. You know, the questions have come up, and I actually expect that it is more likely that they will address these issues. So I think that this is quite likely.

In terms of the second request, yes, the next emergency committee will be pulled up at some time in the future, and then we will give you notice when this is going to occur.

**Lisa Schlein:** If I may, I'd like to move away a bit from the review committee, and I'd like to ask you a status question right now that H1N1 itself has apparently has peaked in certain parts of the world, North America, Europe, and so forth. But it is in the southern hemisphere, and I'd like to get a feeling about what is actually occurring there, that is the situation in Africa, for instance, and some of the other areas which are particularly vulnerable in terms of not having the kind of expertise that, or vaccines, that the richer part of the world has. What is occurring there? Is it of concern to you?

**Dr Fukuda:** Thank you Lisa.

So to give you a quick update, as you mentioned the activity levels of the pandemic virus are relatively low in North America and in Europe.

The parts of the world which have the most activity right now, some parts of the world with increasing activity, for example, we see activity elevated in parts of south-east Asia. As we have mentioned in the past, in west Africa, but also in some parts of [central] Africa such as Rwanda. And then more recently, there has been increasing reports of activity in Central America and then parts of South America. We of course have concerns about what may happen as we go into the winter part of the southern hemisphere. As you rightly point it out, many of the countries in southern hemisphere are the countries who are least able to handle large outbreaks of disease and who have the least resources, and as you know the reports of H1N1 in some parts of Africa, particularly western Africa, have been relatively recent. We did not have reports of actively in western Africa in 2009. There really were more in 2010. And so this is something that we continue watch very closely on. A lot of the efforts to get vaccine out are focusing on those countries in the southern hemisphere. And in fact these are the issues which are raised by the last time the emergency committee was convened. They raised these exact same concerns and questions about the southern hemisphere and in particularly in many of those areas. Thank you.

**Gregory Hartl:** A few more questions and we will call it off.

**Lisa Schlein:** Just to follow up on that. You say that you just recently gotten reports from west Africa about H1N1. What validity is there to the reporting that you are getting, that is, is the surveillance systems in these countries up to the par that you wish it should be, is the monitoring good?

**Dr Fukuda:** I think that there's a two part answer this.

One, I think the information in this particular instance is pretty good. Not as much as we would like, but the information that we have is pretty good and the reason why I say that is that the information comes from surveillance and from studies that are going on which showed that there is a transition from seasonal influenza viruses over to pandemic influenza viruses. And so that change over, we have information showing that in fact the change over was taking place, and so that's pretty good. And then in addition, what was new is that, even though there were sporadic isolates before, it was in the past few months that we got reports of community activity, of disease activity, so in combination, we think that the available information is reasonably good.

But to answer to the second part of the question, I think it is clear that the surveillance capacities still can be made much better. They can be improved in Africa but also a number of other countries, and so this is one of our big aims that we hope to continue moving on over the next number of years, is to improve those basic capacities there.

**John Zarocostas:** Yes, Dr Fukuda, I was wondering if the expert committee will examine the availability of H1N1 vaccine and compare it with the logistics and availability of the prototypes for H5N1, given that there have been quite a few cases of avian this year with high fatality rates which was the initial concern and the benchmark for the pandemic prototype that we have here on H1N1. Is that going to be examined sir?

**Dr Fukuda:** John, I think you are talking about the review committee. Again I expect that the review committee will be looking at pandemic vaccines, H1N1 vaccines. And again, as I mentioned, am not sure specifically what questions they will raise about it, but I think if the general topic, you know, it is a very big topic, and I do not see how they could not address it.

But in terms of the specific question, those, the balance between H1N1 vaccine and attention to H5 vaccines, I think this is, I simply cannot tell you. I don't whether they will make those comparisons or whether they will look at that as an issue or not. So then, I do not know.

**Gregory Hartl:** Last question, Gabriella.

**Gabriela Sotomayor:** Thank you very much Dr Fukuda. Independently of the committee, in your opinion, is the world better prepared if another pandemic comes, the threat, you know the states, WHO everybody? Do you think, are we better prepared?

**Dr Fukuda:** Gabriella, well, here I will jump ahead of the committee and say that. I do think that in many fundamental respects, the answer is yes. We are clearly better prepared. And I say this for a couple of different reasons.

That If we go back, say a decade, go back ten years, to say how are we able to handle things now, I think that the passage of the IHR, all of the activities that went into pandemic preparedness. And I think that the lessons from outbreaks like SARS really changed how the handling of global emergencies is done around the world. For example, we do talk with each other much better, and I think that the actions are better coordinated, certainly compared to a decade ago.

Secondly, I think that if we look at the current H1N1 pandemic, it showed us though that we still have a lot of things to learn how to do things better. I think that for example, how we get information out, how we communicate, how we make risks understandable to people, how we describe things, how we use words like what we call the pandemic, how we are going to be more flexible so we can scale up, scale down more easily, more quickly in a coordinated way. I think simply by identifying that these are really issues that we need to work on, we need to do better. I think already it automatically means that we have a lot of people thinking about these things. And so I think that it is that kind of thinking which leads to making improvements for the future.

So my basic answer is yes, we are definitely better prepared. I think having gone through many of the previous outbreaks that I mentioned. I think that for me it is very clear that we do things better now than we did in the past. It is equally as clear to  me that there are areas where we going to have to continue to get much better. I think that the challenges in the future are going to be more complicated in many ways the world will grow more complex and more linked, and move more quickly. And so we will have to keep up with that, and that will keep pushing us. Thank you.

**Gregory Hartl:** Thank you very much, for today.

World Health Organization

# Transcript of press briefing at WHO headquarters, Geneva
# Dr Harvey Fineberg, Chair, IHR Review Committee

## 14 April 2010

**Harvey Fineberg:**

Good afternoon everyone. I am Harvey Fineberg, I am the chair of the Review Committee to review the IHR  and the H1N1 pandemic experience here at the World Health Organization. I am very pleased to have this opportunity to meet with you at the conclusion of the first meeting of the committee. I expect some of you, perhaps all of you, were able to sit in on portions, if not all of the deliberations over the last three days.

So I will not try to recount the experience on the assumption that you have witnessed it yourselves. If that is not a good assumption, since I can barely see over the railing to identify who is there, please let me know. Is that a bad assumption? Maybe if the others, with your forbearance then, let me just take a minute to describe what the committee's role is and what we are trying to accomplish.

The committee is made up of 29 individuals who were chosen to represent a spectrum of expertise, a variety of backgrounds and experience, a range of countries and regions of the WHO represented, balanced in gender and racial composition, all brought together for a purpose of improving the World Health Organization's, indeed the world's ability to contend with pandemics like the H1N1 in the future, and to improve the functioning of the International Health Regulations.

The International Health Regulations of 2005 called for a review in five years time, of how well they were working. So the committee was convened in part to fulfil that requirement of the International Health Regulations.

Since over the last year and a half, the experience of the H1N1 has been so important and indeed represents a kind of powerful test of the workings of the IHR, the Director-General, with the approval of the Executive Board of the World Health Assembly, elected to combine a committee's function to review both IHR in general, and the performance of the World Health Organization in H1N1.

This three-day meeting was a first effort of the committee to organize its work, to begin to identify the critical issues that would need to be looked into. The meeting had some unusual features for an expert review committee, which legally we are. One of the striking features which indeed is called for in the IHR regulations is that Member States' representatives and representatives of intergovernmental organizations and non-governmental organizations are invited to be present at the deliberations of the Review Committee. And so these last three days, we benefited and interacted from the members of the state parties who were present, who offered their views, who reacted to the deliberations and provided a very important sounding board and set of witnesses for the work of the committee. In the end, it will be the committee's task to present a report to the Director-General, and the Director-General in turn will provide her response to the report, and the two ultimately will be presented to the World Health Assembly, as called for in the IHR regulations.

Our plan is to present an interim report, essentially outlining the approach we intend to take, at the May 2010 World Health Assembly, and if the committee is able to complete its task in a timely way, the report should then, in a final form, ultimately be presented to the World Health Assembly of 2011.

The Director-General, in her charge to the committee, made clear that the committee will have free access to individuals working at the WHO, ready access to all documentation that the committee may wish to examine in relation to H1N1 or the International Health Regulations, will have a complete freedom of enquiry in terms of the areas it wishes to examine, the people it wishes to interview or to hear from, and the topics it chooses ultimately to draw conclusions upon and make recommendations about.

The committee is brought together as a group of individuals not representing any organization, not representing any state, but representing each individual's own best judgment to apply to the questions that we have been asked.

I am here because I was elected by the committee to be its chair, and I look forward in that role to working with you and the press and others in the media who will be interested and wish to follow the work of the committee and to be informed from time to time on any questions that you have in mind about what we are doing and how we are going about it.

So, with that background, let me pause and invite any questions that you may have, and I look forward to talking with you.

If you wouldn’t mind, it would help me — although I have met a few of you, I have not met all of you —, and it would be a help to me if you wouldn’t mind just introducing yourselves, although I presume most of you know all of the rest of you here… but I am the one who does not, so if you will bear with me and introduced yourselves, I would be grateful.

**Frank Jordans, AP:**

You stressed the fact that the committee members who are here as individuals, and indeed got the chance, spoke of the need for an independent and critical review, but I was wondering — if several of the members are advisors to WHO and most of them are government employees of some capacity, what stake will these people have in practice to write something that is critical and independent when they have such a close relationship with the people that they are scrutinizing?

And a quick, specific question: How many of the panel members were involved, in any way, in drawing out what is known as the pandemic phase alerts scale?

**Harvey Fineberg:**

I can respond quickly to the specific, and then come back to the very important general question.

I do not know if any was, or how many may have been. But it illustrates, really, in a specific way, the more general point that you are raising about the backgrounds and potential sources of, let us call it, extraneous influence on the independent and objective judgment of any individual involved in an exercise such as this.

Whenever you are putting together an expert group like this, you are always trying to combine people who are unconflicted with people who are knowledgeable. That is, you want each individual to be free of conflict and also to be very knowledgeable about the subject on which they are advising.

In this regard, I think it is useful to distinguish a conflict which emanates from a financial interest which is, in terms I would use, a conflict of interest — by that, I mean that the individual might hold an interest in a company that might benefit or suffer depending on what is decided or have some other financial stake in the outcome.

As a general rule, it is, I think, good practice — and I believe it is the WHO practice, as far as I understand it — to try to eliminate those types of financial conflicts in the composition of expert committees. When it comes to the positions of individuals, the roles they have, the appointments they may have had in the past, the views that they have previously expressed, the research they may have done, the involvements they may have had — all of these can be relevant and may be sources of what I would describe, in my terms, as bias, by which I mean not an erroneous view, distorted; I mean simply a preceding predisposition based on your experience and knowledge to think a particular way about the question. So, when you compare that to the ideal of an open-minded, unconflicted, unbiased involvement, you have to face the reality that to get the expertise that you want, you have also the possibility — indeed, I would say the usual occurrence — of people with pre-formed views or roles that were related. So the practical question now, to come to your first point, what do you do about that?

And I think the answer is two-fold:

Number 1, you want to expose and make open the biases, so that everyone on the committee as well as others know about the backgrounds, the roles, the previously expressed views, the relevant positions that may have been taken by members.

And secondly, where it may come to the committee's making determinations on matters that specifically relate to the role a member, knowing and having exposed these biases, you can take the step of recusing that member, or members, from the part of the deliberations that relate to their functions. And for us as a committee, we are actually still in the process of identifying all the possible sources of bias — this is a committee that is composed of individuals who have done a lot of things related to public health and including influenza and have, as you point out, positions in government, or had positions in government — and so we are still in the process of gathering this information about the members and our intent is to be able to review that with the committee, so that everyone on the committee is informed about those backgrounds and that we are all more sensitized as individuals to the connection between our previous positions or views and the work that the committee will undertake. So that is the two-part approach: exposure and specific-instant recusal.

**Lisa Schlein, VOA:**

I would like to get a sense of how the discussions went over the three-day period, whether you spoke about H1N1 in rather general terms or whether you were rather more specific in terms of the areas that you should really deal with first.

In other words, did you also give people home work, when they go home and do this? And one more thing, whether there was any kind of a separation made between the way H1N1 is occurring in developed and in developing countries because maybe the virus is the same but the effect is different.

**Harvey Fineberg:**

Let me give you a little more flesh on the bones of the work of the last three days, just to help on the first question.

The committee, as a whole, took advantage of the presence of the Member States to invite them early to offer their perspective on the questions that we were being asked to consider. And these presentations — which were verbally just a few minutes a piece, but can be supplemented by documents and other materials that they will send — helped to highlight a number of issues that the Members States consider important. For example, it was very important to recognize the challenge of containment as a strategy early in the epidemic. That was one of the points they raised. They raised questions about the characterization of the pandemic phases, and specifically, how the question of severity relates to the definition of phases.

They talked about the challenge of equity, which relates to your third question, and the expression of this epidemic in developing as well as in more developed countries. So that helps set the stage and identify a number of critical problems that the committee will need to deliberate on over time.

The committee then organized its work and the bulk of the days according to five areas, three of which dealt specifically with, if you will, aspects or phasing of the pandemic — the first being the preparedness phase, the pre-pandemic issues; the second being what we called in shorthand, the alert phase — that is, everything that leads up through the epidemiology analysis and decision-making to recognition of what is happening. And the third, the response phase, how you respond to the epidemic in its various stages.

A fourth group really dealt with the cross-cutting issue which is central indeed to our conversation, which is communication. And communication we understood and took to be very broad — not simply between the experts and the public, or an organization and the public, but communication at all levels: The communication from world headquarters to regional headquarters, to states; the communication to professionals and to others involved; communication and working relations with the media at all levels. So these occupied a specific portion of our time.

And finally, we did want to attend particularly to the IHR as an important part of our work, the IHR — the International Health Regulations, you are all familiar with that shorthand, I trust… but the International Health Regulations as a topic in itself particularly as it relates to non-pandemic questions.

So these five, if you will, sub-groups occupied a significant portion of our effort. In addition, we had the opportunity to hear some very useful initial presentations from critical areas that we know will be of concern.

Beyond the original overview that was provided by officials of WHO and the legal structures of what we are doing and the overall experience with the pandemic, we had specific presentations on the role and workings of the emergency committee, which is the committee charged with the decision-making or recommendations to the DG about the scale and characterization of the epidemic. And we heard very useful presentations on the vaccine programme of WHO and particular reference to the H1N1 pandemic and the programme of advice on the vaccine area, with the committee that has got the acronym of SAGE. SAGE is a wonderful acronym, I think, maybe the best.

So we took all of that on board. We reflected on how we will proceed in the bulk of our work, and this is where your homework question comes in — it is not just that the staff here have to get home to do the homework, it is that we will probably never let them get home with the amount that we are asking them to do in helping us to prepare and move forward in the next phase of our work.

But in answer to your question, that is how we organized and delved into the questions in these initial three days.

**(Name unclear), Kyoto News, Japan:**

I actually have two questions, both related.

A lot of the discussions you had the last few days seemed quite centred on, not so much the IHR, but the pandemic preparedness plan. So I would like to know, will your committee be reviewing the pandemic preparedness plan?

And the second is, should this happen? Part of the discussions were on the questions of including severity; as I understood is mortality no more included in the definitions of a pandemic.

Now in the 1999 and 2005 pandemic preparedness plans, severity, mortality, morbidity is clearly part of the definition of a pandemic. This was removed in the 2007 and 2009 plan. So should we understand that the removal of severity was a mistake? Thank you.

**Harvey Fineberg:**

You should not understand that from me.

We have drawn no conclusions yet, and the committee's job will be to look at this as well as other aspects of the H1N1 management. But I would stress that what we have done in these first three days is to, in effect, tee up the problems — identify them, characterize them, develop a plan of work. But we have not tried even to draw any conclusions, much less even specific findings. So for example, the history of the definitions and the way the pandemic preparedness plans have evolved is very interesting and important input to the thinking and understanding of our committee, but we have not gotten that far as a committee as yet.

What is evident just from the discussion we have had in these few days, is that the committee will have to come to grips with this specific question of the place of severity in pandemic characterization — that is not to pre-judge what the conclusion may be, but it will certainly be on the work agenda of this committee. Thank you.

**Gabriella Sotomayor, Mexican News Agency:**

To learn for the future, do you think that — because there is some big advertisement here that is pharmaceutical industry… Do you think that it should be revised to their response to the pandemic.

**Harvey Fineberg:** The response of the pharmaceutical industry?

**Gabriella:** Yes.

**Harvey Fineberg:**

Well, it is not the purview of our committee to judge that specifically, but we are looking at the whole of the pandemic. So the behaviour and the expected contributions of all the relevant actors have to enter somehow into our reflections, because even if you were just trying to work as we have been charged to help the WHO: For the WHO to do its work, it has to be able to take account of all the relevant actors. So, in some sense, they will come to be part of our deliberations, but it is, if you said the question, is this in your charge, not explicitly. It is simply what we will have to do in order to complete the work for the WHO.

**German Press Agency:**

The issue of severity and the alert phases that made us uncover the outbreak was probably one of the most confusing parts. At the time, though it was raised repeatedly in April and May of last year that these were the confusing parts, and at the time no-one really listened to the questions journalists repeatedly asked that they were getting from the public. Now it is a year later, you learn lessons for the next time — but is anyone looking into why nothing was done then, when it was obvious that the public was confused about these very things already at the beginning.

**Harvey Fineberg:**

I do not know the answer to that specific question of what the thinking was at that time as of now, maybe we will learn more about this — and in fact, for those of you were not at the meeting, one of the requests that I made to our journalist colleagues, if I may use that word, is to invite your help to us in understanding what the critical issues have been, also from your point of view. I asked expressly, if you could — when you are thinking of critics of the WHO, who do you call? — because we want to hear from the informed critics. And also, we need to understand better what created problems for the media, as well, to do your job? What was it that was difficult and maybe could be better understood, so that the experts of the WHO in the future can be more effective and enable the journalism community to do even better its job. So it is a genuine question that I would re-enforce in this.

Now to come to your point, this back and forth about severity — historically, and then how do people deal with it acutely —; it at least suggests that it is a difficult problem, because if it were a simple problem, it would have been accommodated in an easy way long before. So, what can you imagine are some of the difficulties?

Just to give a suggestion of some of the things that were not discussed in detail in our committees — so I am responding in a way just more generally, but for the sake of the question: When you think about severity, you have at least three problems.

The first is defining what you mean by severity. So, are you talking about mortality? Are you talking about morbidity, or illness? Are you talking about some combination of the numbers and the severity in meaning “severity”? What do you really mean by it? So that is the first challenge.

Second challenge is, how do you measure it? Not simply in theory — but how do you measure it practically and in real time, in a way that can be used to inform your decisions?

And third, how do you account for the variety of severity in different settings at the same time? So you may have a country experiencing a degree of severity very different to another… or within a country, you may have sub-populations experiencing degrees of severity very different to the other.

So all of these initial questions need to be very well appreciated and thought through in order to begin to answer this question — how could you combine severity and extent? It is very interesting — if I could offer a metaphor: When you are dealing with a hurricane, think of it: you know we grade hurricanes; we grade one, two, three etc. Well, that is all about severity. The only measure that determines the hurricane grade is the top speed measured in the hurricane. It is not a measure of how big the hurricane is. The hurricane could be 200 kilometres or it could be 600 kilometres. It does not count that. It is kind of the inverse. It is only about severity; it is not about the size. Interestingly, it is very precisely measureable. You can put in the middle of the hurricane the measuring device, and you can tell, to the kilometre per hour exactly, how much speed is there. You can do it. You can track it visually.

So in the case of characterization, you have inverted what you think is important compared to the flu now, you have very precise measurement. And, by the way — we are all familiar with kilometres per hour. We know what that means. So it is got very good meaning to everyone. So I use that as just a kind of foil to illustrate the difference to certain classification schemes and the challenge, in the case of a pandemic, of applying similar thinking to try to make it meaningful and usable for the public. So this is this all going to be part of the deliberation of our committee.

Question: Just to sort of again go back to the issue of how it was handled — is this committee reviewing the regulations, or is it also reviewing how WHO staff then dealt with the regulations. This will go the level of personal responsibility.

**Harvey Fineberg:**

Both. It is going to deal with both the regulations — and, are they effective and are they usable —, and it is going to deal with the specific actions taken by WHO — or not taken, as the case may be — in reference to management of the pandemic.

The spirit behind this, though, I want to add, is not to point a finger at wrongdoers, or fault-finding. That is not our goal. Our goal is to identify lessons that can help the future — and that is the way we are trying to carry out our work. Thank you.

Any other questions…

**French News Agency:**

There were a few comments from committee members and others during the last three days relating to the nature of the virus, where it comes from. On the one hand, you might have something like Professor McKenzie who, this afternoon, mentioned that H1N1 was a “strange” virus, as he put it. On the other hand, you might contrast that with a rather, sort of affirmative statement from the World Animal Health Organization, the OIE, which the representative said that, I think, […] they came to the final conclusion that this is not of animal origin. Does the public health community know enough about the — or let us put it this way: Are you able to look far enough upstream into the life of this virus, and is that an issue which will be of concern to the committee?

**Harvey Fineberg:**

The committee is not primarily concerned with the origin of the virus, but the background of the origin of influenza as a human disease and the epidemiology of the virus are relevant to the considerations that we are going to try to take.

It is important for us try to be very clear in our thinking and understanding about the characterizations of the virus and the disease. For example, when we talk about the non-animal origin of the illness, it does not mean that the virus did not originate in human-animal interaction — almost surely it did. What is meant is that the contemporary infection of humans is caused by other humans. It is not caused by exposure now to animals. These are two very different things, both true — so that the intent of the statement that it is not animal-transmitted disease is not to characterize the origin historically. It is rather to differentiate the worry which can be falsely assigned to interface with animals or particularly with food products derived from animals, and worry that that may transmit the virus. From a scientific point of view, a pork chop is not a source of swine flu. So this is the intent on the statement about animals and viruses.

So even though it is not the primary responsibility or the main focus, it is in the background. It is part of the, if you will, the gestalt of influenza that the committee has to absorb in its deliberation in order to make what we ultimately come up with meaningful and relevant to influenza in the future.

**Question:**

Can I take an example? For example, one health expert, quite a renowned health expert, told me before this meeting that there are now tests that tend to indicate that there were human cases, or might have been a human case or cases […], in January. So far, the belief and most of the talk has been about March […]. But if you put it another way, if you look at how fast the swine flu, or H1N1 pandemic, progressed in three months, from April: What was happening from the previous three months, if it had been there, and shouldn't it have been detected earlier? And that would have helped the world response subsequently as well… and would have made a huge difference.

**Harvey Fineberg:**

There is a big difference, just again as a general matter — this is commenting on the question, not based on anything we have discussed, because, as you know, we have not discussed that yet — but just as a general response: There is a big difference between detecting an unknown virus for the first time in practice to going back then and knowing what you are looking for, and seeing, did it ever occur previously — were there any evidence that it had occurred previously.

Take the HIV pandemic, as a counter-example. The HIV pandemic burst on the public scene in the 1980s. That is when people became aware of HIV. With the first cases — mysterious, originally in the US — it was called Gay-related Immuno-Deficiency Syndrome. That was the first name of it. The virus itself was later identified and after that, historically, cases could be detected by means of serologic sampling and other mechanisms even decades earlier. So these are two very different propositions: detecting historically an earlier occurrence when you know what you are looking for, and being able to detect, for the first time, a new outbreak or a new condition.

Now it would be astonishing, it would be, in fact, inconceivable that the very first human case would be detected. That would be like saying that you actually felt the first rain drop that fell on Geneva. You know, that is hard. You have to be in the exactly in the right spot and it has to fall right on your nose, and then you know it is raining. But if it starts to pour, you can be pretty sure you are getting wet.

So in a similar way, what you need in a surveillance system is not this ideal that you can detect the very, very first case. But you need earlier and earlier capacity not to overlook the clinically evident cases that can reveal a new outbreak and give you the maximum time for preparation. And the two are not at all incompatible, going as early as you can and recognizing you cannot get the first.

**Question:**

I was wondering, sir — do you have experts in your 29 members with backgrounds in pharmaceutical production, marketing and logistics? And also if you intend to look, among your deliberations, at the change of the terminology — not to use the word swine flu — which occurred overnight; and two other agencies were involved in the decision with the WHO out of the group.

**Harvey Fineberg:**

On the first question, I would say that to my knowledge, there is no member of the committee with deep expertise in the manufacturing and production of vaccine. I state that with a qualification ‘to my knowledge’ because I do not want to misrepresent the backgrounds.

Having said that, it is also the case that there are many, many types of expertise that the committee will need to seek out to inform itself, but that cannot be represented in the membership of the 29 individuals who are present. So it is an example, but it is just one. There could be quite a large number of those.

On the naming conventions: This came up, actually, in the presentations in the first phase of our meeting, and it is clearly something about the management of the alert phase that we will need to consider.

**Jonathan Flynn, Reuters:**

[…] Can you just say what the next steps for your committee are — the timetable for your next meeting…?

**Harvey Fineberg:**

The committee intends to meet again sometime during the last week of June, that is the week starting June 28 and extending to July 2. We do not know yet which three days will be best, but we expect to have a three-day meeting during those five days. So that is our next formal step.

In terms of the work plan, we are intending to continue to have a kind of conversation on the topics by the members of the committee. We have a lot of work for the secretariat to do in preparation for our deliberations at the next meeting.

And beyond that meeting, we have agreed that we will schedule at least a third meeting, tentatively set for the week of September 27. And that again, which three days of that week ending on October 1, we have not chosen, but it will be during that week. That is our current plan.

**Question:**

And when do you expect you should release the final report?

**Harvey Fineberg:**

If we are able, we would strive to have our final report out in time for the Director-General to present it formally to the World Health Assembly of May 2011.

**Question:**

I was just wondering if you could talk about whether the committee will address, or has already begun to address WHO’s role in facilitating technology transfer and capacity building to improve access to vaccines in countries without the manufacturing capacity, including Intellectual Property flexibilities, if they are necessary.

**Harvey Fineberg:**

The presentation that we had today on vaccine programme at WHO touched upon these questions, and the committee in its posing of questions afterwards did include a desire for more information on the issues of capacity and on the pre-qualification questions. So we expect we will be investigating those along with our other topics in the coming months.

**Question:**

Out of curiosity, I am wondering how you will approach what appears to be this very broad topic — it what may have landed you into this committee exercise to begin with — as to whether the pandemic has been hyped. Around the world, I have been reading reports which are beginning to scapegoat the media for having hyped it; I read something else about medical workers, health workers refusing to be vaccinated, and they should know better — maybe.

So have you been dealing with this, and broadly speaking — how do you approach this, or is this something that magically comes together after you have done, put together all the elements of your investigation?

**Harvey Fineberg:**

On this question of scapegoating the media — after all, turnabout is fairplay. So you have to expect you are going to be the subject of accusation in the same way. It is feeding the hen that bites you, is it the opposite? So yes, you just have to expect that it is part of the territory that comes with being responsible journalists and even more so if you are an irresponsible journalist, but that is the just the way the world is.

Now we are very mindful that a number of criticisms have been levelled at the WHO and, more generally, about the management of this pandemic, and we want to give a hearing to those. We want to take account of those. We want to consider those, and indeed today, I also asked our journalist colleagues if you would be willing to share with me, you know the answer to the question — when you are looking for a critic, who do you call —, which was really a way of asking, who do you feel is informed and critical about the process? Because we would like to hear from them. We would like to understand what their criticisms are, and the basis for them. We want to be able to take that into account. We want to face up to those. We are not here to either defend or to prosecute the WHO. That is not our job. We are here to find out as best as we can and in as truthful a way as we can: What are lessons that we can learn?

And finally, we will take one more question.

**Question:**

Since we are in the early stages of this whole process, I will come back to your question of the composition and the purpose of the committee, since there really aren't that many questions that we can ask at this stage about the content of your deliberations; you have only just started. I still find it difficult to understand how this committee can be described as external committee given the relationships between the members and WHO and governments. I mean, no US Senate hearing or British parliamentary committee hearing would operate in this way. They would have people like the members in as witnesses, but there would have to be a line drawn between those with any interest because they worked on the whole process that is being scrutinized, and the people who are doing the scrutiny.

**Harvey Fineberg:**

I will offer my take on it, but again, I am one of the appointees — I am not the appointer, so I can only give you my view about it.

I believe that when the term 'external' is used in describing this committee, or this type of committee, essentially what it means is, non-employees. It means people who are not employed or in the payment of the WHO.

Now it does not mean utterly disconnected. It did not rule out anyone who has consulted for or helped advise either governments or WHO and — so, that was the distinction that I think would apply just to the definition of that word.

If you said, well, how can it be truly independent in judgment because it has had these previous connections — if that was the thrust, then I would return to my discussion of bias. We have to recognize that every one of us brings predispositions based on our experience, our knowledge base, positions we hold or have held, and we are trying to dealt with those by exposing and by recusing in specific instances. Whether that is an adequate response to the demands of independence of thought is perhaps a judgement I would acknowledge. It is not an absolutely clear-cut case. I think the reality is, if you are trying to get that combination of expertise and freedom from conflict in a financial sense, you deal with that by acknowledging, exposing, and appropriately recusing, in specific circumstances, the members. At least, that is the implicit strategy behind this selection. That is as much as I can say.

**Question:**

I will give an example to ask the question.

Mexico was the most concerned country. And there was a ceremony here that the Minister of Health came and donated the eggs to the world to do the vaccine. So after that, Mexico asked to the pharmaceuticals, to the laboratories, to have the vaccine. And the industry said, we cannot give you any because there are countries that have pre-ordered the vaccines, and we cannot give it to you.

A lot of countries are throwing away vaccines. A lot of countries do not have it! This should not be happening in the future, in another emergency.

**Harvey Fineberg:**

You could have been speaking on behalf of some of the presentations from the Member States in your comments, because these questions of equity, fairness — these were raised. And I do not know how we are going to ultimately come forward with fresh ideas on how to improve on this, but I can assure you that the committee will do its best to look at the question.

With that perhaps, I would thank you all for your interest and willingness to be here today, and I look forward from time to time to be able to respond to your questions as we go forward.

So thank you all.

# Transcript of press briefing at Palais is de Nations, Geneva
## Dr Harvey Fineberg, Chair,
## International Health Regulations Review Committee

**19 May 2010**

**(NOTE: sound quality of the audio file was poor in places as noted in the transcript)**

**Harvey Fineberg:**:

Good afternoon everyone. I'm Harvey Fineberg. I'm the chair of the committee to review the function of the IHR (International Health Regulations), and the H1N1 pandemic experience. I am pleased to have this opportunity to meet with you and to try to respond to any questions that you may have.

Many of you I know, are aware that the committee was formed earlier this year. That we had our first meeting here in Geneva, approximately a month ago, and that our second meeting is anticipated to be held at end of June and the first two days of July.

We are here represented by myself in order to hear and participate in the portions of the World Health Assembly, that is related to IHR and influenza, and also as all of you know, from being here, it is a marvelous opportunity to see a great many people and to have interactions informally as well as in formal ways.

But today, I am pleased to be able to be with you, and to be able to respond to any questions that you may have about the work of our Review Committee (RC). So with that, let me invite any questions from those who are here.

**German Press Agency:**

How much are you actually investigating the issue of the WHO's links with industry? How much has that really taken up time and efforts from your committee?

**Harvey Fineberg:**

The committee is well aware that there is concern that has been expressed about the potential influence of industry on decision-making at the various advisory committees and in the WHO more generally.

We began to explore this issue with some discussions at the plenary sessions, even at our first meeting, hearing from the chairs of the SAGE committee, this is the vaccine strategy committee, and also from the Emergency Committee chair, who dealt with decisions about the pandemic. We expect very much to continue this exploration including discussions with representatives from the industry side, and we are very attentive to try to understand and to identity the nature of any relations, the degrees of influence as may have existed and the basis for that, and also to take account of that in conclusions and recommendations. As of this time, we are still in the information gathering phase. I would add if I may that, if any of you has information about the relations that you feel may be helpful to the committee, we are very eager to receive that information, and it can be in the form of materials that you have or communications that you are aware of, or people that you believe would be helpful for us to learn from, any of that would be very welcome. Would you like to follow-up?

**German Press Agency:**

If you were to find the link, what would that lead to, and would that lead to a more general review of WHO's link to industry?

**Harvey Fineberg:**

What do you mean by find a link?

**German Press Agency:**

Well, you say the degrees of influence that may have existed, let's say there are degrees of influence in some form.

**Harvey Fineberg:**

I'ts a hypothetical of course, but let us presume for a moment the premise of your question, what if there were, would that have wider implications? If it did exist, then our committee is fully authorize to make recommendations to the Director-General, to the State parties, the constituents, who are responsible for the agreement of the IHR, to take appropriate action as we deem it to be indicated. So there is no restriction on our committee in the nature of the recommendations that may follow from our conclusions.

**Frank Jordans, Associated Press:**

You said there are no restrictions on the nature of the recommendations. Can you tell us if there are any restrictions on where you can publish the recommendations ---?

**Harvey Fineberg:**

Well this committee is a committee whose report, formally, will go the Director-General, and the Director-General will transmit a report and potentially additional comments of her own to the World Health Assembly next year. That is the plan.

I have been assured personally, that the report of the committee, in its entirety, will be a public document. So I expect that that will be the case. That does not mean that the DG will accept every word of the document. But it does mean that the committee is assured that its conclusions and recommendations will be a matter of public record.

**Robert Parsons, Geneva Courier:**

Dr Chan told the Executive Board in January there was no problem in WHO's handling of the H1N1 pandemic, that the whole problem was simply media and people seeking sensationalism and lies and whatever. Are you going to pursue the aspect that, are you going to look into that considering that was her official statement to the Members of the Executive Board, that it actually all lies with the media, and that the media had --- it and ---- .sensationalism seeking to sell newspapers and so on.

**Harvey Fineberg:**

I was not present at the time the DG made that comment, but I can tell you what she has said to me, and to our committee, and in her approach to us she has explained consistently that she wants an open, honest, and transparent assessment as objectively as we can make it about what happened, what was done well, what was done poorly, and the aim in all of it is to identify lessons to improve performance in the future.

This is not to exonerate the role of the media, but it is also not diminish the responsibilities for what went well and what went poorly, in decisions, and in actions at the WHO and at Member States. Our committee is mandated to look in any aspect of the experience that we think bears on lessons for the future.

Just a personal aside, even if you believed that the nature of the reporting about the pandemic in particular instances was a problem, then it suggests to me that you need to face up to the importance and working more effectively with the media and in reaching the public so that accurate, timely, relevant information conveyed in a correct way that is correct in terms of its implications, in terms of the context, or in terms of what means for health and what it means for society, that all of that is done in a successful way. And if the inquiry that we are undertaking leads us to that direction of the importance of the media and the role of the media, it does not mean that there is a fault in the media in my mind. It simply means that the process of conveying and reaching that public was deficient in one way or another, and that can be approached in many ways. So it's not to me a matter of looking at the media as a source of a problem. The media is a vital conduit between experts and policy makers and the public and vice versa.

**Robert Parsons, Geneva Courier:**

Yes because the WHO spokesperson has denied that the WHO changed the definition of a pandemic, yet the 2005 guidelines on the WHO web site, they were sent out to Member States are at variance with what was used to define the pandemic. For example, 7 some million deaths in a very short period of time --- hundreds of millions of hospitalizations ---. How do you intend to deal with this? Will you take this into account or is it a fact that there was no change in definition?

**Harvey Fineberg:**

The question of the characterization of a pandemic and how the practices about the characterization may have varied over time and for what reasons, all of this is a very important part of the understanding that the committee has to reach. So we are very much attending to this set of questions around the way a pandemic is described and characterized. You mentioned the historical feature of how it may have been different one and time and changed in another time that is one dimension of this. But another very important dimension implicit in that and certainly important looking ahead is the question of characterizing severity as well as extent. So that you have pandemic spreading how quickly, is a different question from whether and to what degree it is producing deaths, illness and other problems. And the committee is going to have to come with grips with all of these aspects of the characterization: historic, and this question of severity, as well as spread.

**John Zaracostas, British Medical Journal:**

You mentioned that you have assurances that your report will be a public document. Will that included all the material forwarded to the committees: epidemiological data, etc? Will that be included as attachments in annexes? Because during the first year, a lot of these epidemiological data that was coming in to the WHO from Mexico, the US, Canada, was certainly not shared with the media. Thank you.

**Harvey Fineberg:**

In response to the question, first the report itself will be public. The report is going to be likely a document that will include a number of annexes which will range across the relevant but not intrinsically important material contained within the report. So there will be a number of annexes. We have not as a committee yet developed a full conclusion about accessibility to additional materials as may be for example web based. But one thing I could say that we are aware we will want to have access to certain confidential documents that may be in place here at WHO or elsewhere. And by virtue of our examining them, they do not automatically become public documents. So there will be some materials I know we will be looking at.

**John Zaracostas, British Medical Journal:**

Epidemiological documents, hard science…

**Harvey Fineberg:**

Yes, I do not know the answer to what the policy is about that. But I am confident that we will have access to all of that information. What I can answer is whether it is or is not part of the public record or would be become part of the public record, I just do not know.

**Lisa Schlein, Voice of America:**

Once you have finished your investigation, will, among the answers, will there be answers to the question or the criticism that perhaps this whole pandemic has been over-blown? And how do you actually evaluate whether, indeed, it may have been over-blown or not?

**Harvey Fineberg:**

The question of whether a pandemic is over-blown is connected to the earlier point about the characterization of a pandemic. When you are approaching this question, how do you decide? Even though we are looking back at the experience, the important posture is to take a proactive point of view, namely what was it what was known at a particular point in time when a decision was made about a certain character of the pandemic. And what we want to avoid as a committee is applying a, what I will call, a mindless retrospective view which is simply saying, well we learned this much happened afterwards, why did not they understand what was going to happen when the reality in prospect is that uncertainty of a situation may have been very much more prominent than later resolved into a reality.

So the characterization of the choices made as insufficient, appropriate, over-blown, or something, will always have to be taken from this prospective posture understanding what was known, and I should add, what was knowable, because it is also possible that information at that time was not availed of, that could have better informed the decision. That is very different from information that only became evident at some subsequent time and could not have influenced the earlier choice. So that is how we are gong to try to approach the question.

To do that, you really have to have a very fundamental understanding of what was known at what point in time. And so part of the work of the committee with the help of our Secretariat is identifying the sequence of events and information, so that we can make our judgments about the choices made based on the actual knowledge at that time.

**Neue Zurcher Zeitung (NZZ):**

--- in the language of tabloids, what happened was that some experts from the pharma industry somehow worked on the WHO and -- made --- this pandemic -- made suggest that the pharma industry goes ahead producing much vaccines and making a lot of money -- if you go the bottom of the scene the interface is the experts. The committee wants cutting-edge knowledge about research about pandemic and vaccines, etc., so somehow it wants to be as close as possible to the research which has been done by the industry, because they have the money to do it. And there you sort of establish an intrinsic link, and may be a linkage of interests. How do you tackle this?

**Harvey Fineberg:**

Let me talk about the general point and then come to the application, if you will, to this instance.

As a general point, any time you have an expert advisory committee, you are trying to keep in mind two things. One is you do need people who actually have expertise, so that means the experience, the training, the professional knowledge, that is relevant to the task. And secondly, you want to keep the committee as free of possible from a conflict of interest, which is in the terms I'm using, a financial interest in the outcome that follows.

And so when you look at the qualifications of individual participants in such activities as expert advisory groups, you really have to ask the question, are they experts and were they conflicted? Two questions.

This is now coming to the specific. I do not yet know what the judgment would be looking at any individual members of the decision-making bodies. But I do think that it's a relevant question for our committee to examine. Because it does get to the heart of this allegation about undue influence from industry.

What I can tell you if you go back to the first meeting, the chairs at least of both the SAGE and the expert advisory group were quite adamant and straightforward in rejecting any direct influence by industry on any part of their decision-making as far as they could know. But I realize you are raising a more subtle and slightly different point which is not whether the industry came in and made undue influence directly but whether the individuals who were part of the process already brought with them, a predisposition to make decisions that would be in the interest of the companies. And we have to look into this.

**Stephanie Nebehay, Reuters:**

Has the WHO Secretariat began to share with you already the experts who -- have they began to share with you confidential documents on the early part of the process --- ?

**Harvey Fineberg:**

What I can say is that, any document that we have requested they have made available to us. What I cannot tell you because I do not really know whether anything we have been shown was at some point considered confidential or still is. So I cannot specifically respond to your question. But I can tell you that the Secretariat is being extremely forthcoming in making available to the committee all materials that we have requested. And in fact, they are going beyond that because literally this morning, I had an opportunity to meet with a number of representatives of the Secretariat of the relevant clusters here at WHO. And they are providing additional materials that are in a way compiled and made available for the benefit of the committee beyond even what was already in place. So we are getting access to everything that we have asked for, preexisting information, and even more.

**Gunilla von Hall, Svenska Dagbladet:**

--- you will take appropriate action to recommend appropriate action. What does that mean?

**Harvey Fineberg:**

Well concretely, it depends on the nature of the link, which is why I ask my question, what do you mean by a link?

What I would say as a general matter, we want to offer recommendations that are key to the problems we find. We want to offer recommendations that enable the world, WHO, and the nations to do better the next time, and we are confident there will be a next time, at some point.

So what exactly would we say under hypothetical finding is really too hard to answer concretely. It depends. And what I would say as you follow the process, as I hope you will, and as you see the nature of our findings and conclusions, you will be able to judge, whether the recommendations that have followed are indeed appropriate to the findings and conclusions, and that will be a mater of judgment that I hope you will exercise.

**Frank Jordans, AP:**

To your knowledge, what kind of documents are classified documents?

**Harvey Fineberg:**

The only ones that I am personally aware is that some of the agreements with industry that we would like to examine have been considered confidential agreements. And I do not really know more about that at this point, but that is what I understand, that's what I meant by confidential documents. I did not have in mind epidemiological data.

**Stephanie Nebehay, Reuters:**

So the documents are referring to donations or --- ?

**Harvey Fineberg:**

No, no. You may be right that there other kinds of documents that are confidential that am not aware that they are confidential. But the ones that I was aware of in response to this question are some either contractual or letters of understanding with industry that have been considered private communications.

**Lisa Schlein, Voice of America:**

I was wondering, the next meeting that you are having at the end of next month. What is the next level of work that you will be doing that is what particularly will you be probing which is different from here, or moving the process?

**Harvey Fineberg:**

As some of you are aware in our first meeting's conclusion, we decided that we were going to proceed really along five tracks in terms of our work plan. Three of the tracks dealt with the kind of sequence of H1N1 response starting with the preparedness then the question of alert and then the question of response. So those were three of the tracks.

The fourth is a cross-cutting track of communication, that gets to the question about the media, but communications in its broadest sense as many actors, many communicators, many communicated-to, and understanding the responsibilities and the actions at all of those levels.

And the fifth was the IHR regulations and its performance with some special reference to experiences in addition to the H1N1 because H1N1 is also a kind of test case for the IHR. So what the committee has done, in the course of the interval between our first meeting and our second, is try to work in sub-groups, attempting to enumerate the key issues that we need to explore in these five areas. And that's, part of that process is elaborating issues and part of the process is winnowing the issues to the one that are really important.

And then what we hope to accomplish at our second meeting, is particularly to include in the plenary sessions, of the second meeting, the opportunity to hear from witnesses to the committee individual with competencies one way or another of the areas that we consider important that we want to make for the injury. So for example, some of the issues we have already raised around the industry and its influence, or around the definition and characterization of a pandemic, and potential around communications questions. All of these could be a part of the agenda for this next meeting.

We are still in the process of refining the issues to know which of the ones that we are concerned about. Do we want to put the highest order priority for the precious time we have together on these three days, June 30, July 1 and 2, and that we are going to do.

I might add here when it comes to the meeting, the next meeting, what I am going to propose to the committee is that in the plenary sessions of the meeting, we once again open the meeting to the press. As you know, we took this step in the first meeting. I think it was good choice then, and am hoping that the committee will go along with that in our next meeting, but I emphasize at this point that it will be a proposal that I will make to the committee and the choice will be at that time.

**Lisa Schlein, Voice of America:**

Sorry are there 18 members?

**Harvey Fineberg:**

No, there are 29 members appointed to the committee at this time.

**Isabel Saco, EFE:**

At this point do you think that there will be --- when do you think you could be able to give some conclusions and advice on the recommendations?

**Harvey Fineberg:**

Our aim is to have the report presented to next year's World Health Assembly. So that's really the target.

We have discovered that these are very complicated issues, some of them, and my hope is that we will be able to complete all of our fundamental assessments in that time frame. But another point that the Director-General has made clear to us is that, whatever the committee requires, in time and effort to do its job thoroughly as well as fairly, she will endeavor to make available to us. But our goal is to have the report presented a year from now.

**Isabel Saco, EFE:**

So not really to have some really in-depth information from you before that date?

**Harvey Fineberg:**

I would say, that is correct.

**Question:**

You said you would --- witnesses to the committee. Who are you talking about, witnesses?

**Harvey Fineberg:**

I mean experts or individuals. Witness is may be too legalistic a term, but its people who will be called to offer their views. Individuals that we will invite to come to Geneva to help us to understand something, and the something could be definitions of pandemic, it could be the role of industry, and it could be a number of these key issues. That is what I meant. Thank you for the opportunity to clarify.

**John Zaracostas, BMJ:**

I was wondering, sir, if you can elaborate, how can you deal with the situation that in your committee, you have members who are part of the Emergency Committee that was instrumental beginning from the various phases? What are the terms of reference and in what areas will they step back and be unable to comment and at the end of your report, will these members be identified and will the report been written in a way that each intervention by a member of the committee can be identified or will it anonymous??

**Harvey Fineberg:**

Let me get to the last question first. In general, the report will be a report of the committee. Every member of the committee will have an opportunity if they dissent from any part of the report to offer their dissenting position. So that will be a part of this. If there is any part of the report from which members of the committee for any reason, and I stress any reason because, let me come back to why I say that, is recused, then that will be explicitly explained also in the report.

When I say for any reason many members of this committee including myself, have played some kinds of role in respect to H1N1 nationally or internationally over the course of the epidemic, so I think it is quite important that all members of the committee understand that background and experience of all of us, so that the committee can know in effect what each of us brings by way of that experience and background to the deliberations. And I will tell you that we are aware, we became aware, those of us who were appointed to the committee of the, let me say, joint roles, that some have played for other WHO committees as well as our review and we are very mindful of needing to come to grips with that, but I believe it is a more general problem that we also have to u9dnerstand and approach and because it could be that there are many different ways in chichi any of us could bring predispositions to this, and we want to expose that and make sure that we within the committee are fully cognizant and aware of it.

**John Zaracostas, BMJ:**

If I can rephrase my question, for instance, on the segment concerning the phasing. If you have got members of your committee that were instrumental in the decision--making for this segment, will they step back and say, look I cannot offer an opinion here because, I was, you cannot be judge jury if you are a decision maker on going from five to six you can't be a critic and review a decision. That is just basic jurisprudence, is not it?

**Harvey Fineberg:**

Let me state it a little more generally and essentially to your point.

I agree, you cannot serve effectively as both the actor and the judge. So I think in such instances which may apply in a number of different circumstances. I will give you an example personally.

If there were, if the committee were to make some judgments about decisions taking in the United States where I live, and where I served in an informal role about advising the US Centers for Diseases Control, the was some question about relationship between that agency and WHO at some point. Then that would be a topic and an issue where I personally would feel, I would need to at the minimum explain it to my fellow committee members and if it were an issue where I played a role in a decision, I would have to recues myself.

So I think the logic of this recusal process would apply across the board to anyone who has a joint role so to speak on any matter that would be coming before the committee.

**Gabriella Sotomayor, Mexican News Agency:**

Something is not clear to me. Are you going to review the industry, are you going to investigate them, or only WHO and its Member States?

**Harvey Fineberg:**

Let me be clear on this. We are not here to investigate the decisions taken by industry per se. So for example, let me just give you a hypothetical.

Industry decides to have built a factory in a particular place and not in another to produce vaccine. Why did they do that? Why did they build it there? We have no mandate to investigate. Why was industry better prepared in place X or in place Y? That is beyond our scope.

But when it comes to the relationship of industry to decision-making, in the course of this pandemic, then that is relevant to us. And so we are not investigating industry, we are investigating a set of decisions with all of the relevant actors as each decision took place. So that will be our guide.

**Gabriella Sotomayor, Mexican News Agency:**

--- are you going to follow the money?

**Harvey Fineberg:**

Well, I suppose in general it is a good advice, but I'm not sure, you mean, to see who made money from this entire episode and there fore what did that mean? It is not a bad strategy. I do not know that it will be a complete strategy for us because there is so much of this that in a way surrounds and precedes the money. I think that, I understand that there is a tendency, one of you said before, you know, to read a typical news paper, this is a simple line of the story. People made decisions to produce money for particular businesses and we have to take that seriously. But I don't think that it is a good complete strategy for our inquriy.

**Stephanie Nebehay, Reuters:**

--- how many of the Review Committee members -- ?

**Harvey Fineberg:**

Let me say that the, what my position is, is that every member of our committee, of this committee, must reveal their associations to the committee. Now what will be the decision about that depends again, contextually, on what was the specific association or role I revealed mine here, but it may be different for different people.

**Question:**

-- are you still not aware of how many --- ?

**Harvey Fineberg:**

I will say that I was not aware before the first meeting of any and so I learned at the first meeting also about the dual positions of some persons. I am told that it is more than Dr MacKenzie. So these are things that we have to attend to.

**Question:**

--- ?

**Harvey Fineberg:**

I do not think we have formally extended invitations as yet, but I can tell you that we are very interested in hearing directly from representatives of the industry. Now who exactly it will be, I cannot tell you at this moment, but this is of great interest to the committee.

**Robert Parsons, Geneva Courier:**

A communication question: there were reports from Mexico that said that illnesses of influenza were actually the results of --- conditions of pig farms there --- are you going to look into the aspect of --- not verified --- ? Are you in touch with the --- Council of Europe that is investigating this?

**Harvey Fineberg:**

We are aware of a number of national investigations, about the performance of the individual country on H1N1. Japan, for example, spoke of the inquiry that they are doing and their presentation at the World Health Assembly. We hope to take full advantage of all of these.

I do not know the exact status of a Mexican review or its performance, but I would say that the kind of detailed question that you are raising at the outset on choices made in Mexico would be more a matter of a national review of Mexico than it would for our committee to undertake.

There are details of management, use of information, decision-making, in every country that dealt with this which is just about every country. But that is beyond the --- of this committee.

Thank you all very much.

# Transcript of press briefing with
# Dr Harvey Fineberg, Chair,
# International Health Regulations Review Committee

## 2 July 2010

Good afternoon, everyone. I'm Harvey Fineberg, Chair of the Review Committee to examine the International Health Regulations 2005 and the H1N1 Pandemic of 2009. Here at the World Health Organization, we have just completed our second meeting of these last three days. I wanted to say just a few words about what we did at this meeting and then open up for any questions that you may have that I can respond to.

The Committee, as you may know is drawn by members from around the world. There are 27 of us in all. We organized this meeting to have an opportunity at the plenary sessions to hear from a number of individuals who could inform the Committee from their perspective and experience about the questions that we are being asked to answer. To remind all of you, the Committee is charged with a request to review how well the International Health Regulations are working. One of the big tests of those Regulations was the 2009 H1N1 pandemic but they apply to many other incidents and emergencies for health and so we are examining how well they are working, and then specifically we have been asked to examine the experience with the H1N1 epidemic of the role of the World Health Organization, and others, in face of the pandemic to assess not responsibilities or blame but really to attempt to identify lessons that can be learned to improve our future performance. That's the purpose.

At this meeting we heard from individuals representing quite a spectrum of backgrounds and perspective. We heard from a number of leaders in different countries who were responsible for carrying out some of the work related to pandemic preparedness and response. We heard from individuals in France, in Canada, in Mexico, in the United States and some other countries. We heard from representatives of industry who were involved in the production of vaccines and drugs, representatives from pharmaceutical manufacturer associations as well as from individual companies who could convey to us their experience. We had the opportunity to speak with one of your colleagues, a journalist, Dr. Benkimoun from Le Monde who was particularly helpful in conveying the difficulties of reporting in a subtle nuanced and accurate way, the challenge of decision making under uncertainty and that was very helpful to the Committee and we also heard from a number of well known critics of the performance of the World Health Organization and indeed of the world, in the face of the pandemic. These included Dr Thomas Jefferson who is with the Cochrane Collaborative. Also Mr Paul Flynn who is a very prominent European critic and with Fiona Godlee who is the Editor of the British Medical Journal and has written and editorialized about procedures and practices relating to decision making on the panedemic.

The format for this meeting was a very intense series of interviews. We spent a total of 20 minutes with each of our interviewees. We forwarded them the opportunity for a brief opening statement, then they responded to questions for as much time as we could accommodate. We expect that many of them will have requests for follow up questions and the answers which they are uniformly agreed to do. We learned a great deal. Right now the staff of the Committee is trying to assemble the main points to distribute and share with the Committee Members so that we can digest everything that we learned. At the same time we know very well that we heard only from a fraction of those who can provide valuable information and our plan looking ahead, includes the decision to hold an additional meeting beyond those originally scheduled - the next meeting then will be in September. We have the tentative dates of September 27 to 29 and our purpose of that meeting again will be probably similar in format to this with the plenary sessions including the opportunity to hear from individuals who can inform us. We are particularly eager to hear at that meeting from some of the responsible officials at the World Health Organization and other leading responsible public organizations. We want to hear particularly from representatives in the developing countries who dealt with the pandemic and are responsible for the International Health Regulations. We would like to hear from additional journalists and we would like to hear from representatives of some other organizations such as the European Centres for Disease Control, other places that were involved in, and can help inform us.

We still have a timeline for our Committee's work intended to produce a report and complete our work in time to make our formal submission to the World Health Assembly in May 2011 and that’s still our goal and our expectation.

So with that basic background let me invite you to pose your questions and I will do my best to respond. We will just start here on the left and work our way round.

**Robert James Parsons:**

In listening to the discussions what struck me was the vast chasm between those who had very little if any criticism and those who had criticism. Those who had very little criticism said thanks WHO for its help and whatever but never address the questions that the critics levelled at them. Dr Jefferson talked repeatedly about the lack of figures for example. Mr Flyn and Miss Godley also raised very serious questions. None of this was ever touched on by any of the others and so they are just questions hanging in the air. How do you figure you will be able to conciliate these two because you have got two extremes. One that seems not to want to deal with anything controversial just to say thanks we are grateful that you were trying to do a good job. And the other side that is saying you fouled up repeatedly.

**Dr Harvey Fineberg:**

The Committee in structuring these discussions did not purposely, did not structure it as a debate. We were not trying to hear people challenging one another at this meeting. What we were intrerested in trying to do is to elicit from each of our informants, each of the people who were willing to come and speak with us, their perspective, their ideas, their questions or their experience. Some of the people as you describe in positions of Government or others talked about their perceptions of success and value of interactions. Others who are the critics raised the critical questions. But we didnt ask the non-critics to respond to the critics nor did we ask the critics to respond to the criticism of the critics.

**Robert James Parsons:**

My question is what are you going to do?

**Dr Harvey Fineberg:**

So what are we going to do? We are going to have to come to resolution in our minds as a Committee. How can we do that ? Well part of it is that we are looking at a set of materials that we have been assembling about the background. The policies and procedures and practices of organizations including the World Health Organization. We will have the opportunity at our next meeting to hear directly from some of the officials from the World Health Organization who are in a better position to respond to certain questions than for example a Senior Health Official in Mexico whose criticism is not really levelled at him. And we have available to us already, materials where there are written responses in part to some of the criticisms. So for example the World Health Organization has posted response to the report that Mr Flyn co-authored. Other publications, we didn’t hear for example from the Editors of Nature. Nature Magazine has published a number of editorials posing their point of view critical of some of the critics. So we have many avenues to look at. Our job as a Committee is not going to be to specifically to resolve every controversy what we I think need to do is to understand the nature of the criticisms with the goal of using those criticisms to help gain lessons for the future. We do need to make some judgments ultimately about our sense of the validity and relevance of the various criticisms. That’s part of the job this Committee is going to have to do. I hope you didn’t come to the gathering with the idea that we were expecting others to do that work for us. We have to do that. Yes.

**John Zarocostas:**

Good afternoon, with apologies for having stepped down the other day. With reference to the epidemiological evidence what has come in to the Committee, will that be posted in the public domain? As journalists we have a problem that there isn’t a website where evidence that’s going forward before your Committee is not being shared in a public forum or on a public website is that being set up. For instance various submissions that you have mentioned that have come in, since its a public enquiry, should there not be a public website?

**Dr Harvey Fineberg:**

The Committee intends in its Report to include ultimately a reference set of materials that will mostly be in the form of electronic web-based material that will be available for perusal or examination in depth if one wishes, relevant to the work that we are doing.

We are getting a great variety of submission from individuals or sometimes from organizations. We are not posting those at this point in a public site. At the moment we are using a system to help inform and communicate among the Committee Members but ultimately as we produce our report all the relevant materials that found their way into our deliberations will be made part of the public record so it will be available at the time our Report is available.

**John Zarocostas:**

Not before?

**Dr Harvey Fineberg:**

I don't want to promise that.

**John Zarocostas:**

I was thinking of the congressional system where for instance you appear before our Committee. You present your statement for the record and then you take QandA.

**Dr Harvey Fineberg:**

Now lets take the case of the presentations here. We didn't in advance tell every presenters that their presentations would be posted in public. Some of them may not have expected or may not have expected that. We did tell them that we expected the press to be in present at the time that they were interviewed but we didn't request their permission to post what they submit publicly. But I think if I could take the question in the form of a possible suggestion, I will look into it and see whether we can, how much of it we can make public because the goal, let me say in that spirit, the goal of having these interviews in the plenary sessions before all of the journalist community and the state parties was to have a degree of openess that essentially said you have heard everything that the Committee has heard. That doesnt mean you are going to come out the same place the Committee comes out but you will know what we had to work with and what the burden of our Report will be is to explain the reasoning for the conclusions that the Committee ultimately reaches. Yes.

**Frank Jordans, AP:**

You stressed several times in your opening statement that this was not about finding blame it was about learning lessons for the future situations where World Health Regulations might come into play. Now I think the public will probably expect some sort of explanation and possibly verdict of what happened during the outbreak or the course of it. Will you be presenting anything that goes at all in that direction? I mean something that tells the general public, you know, this is what happened and this is what should have happened and this is why it didn’t happen?

**Dr Harvey Fineberg:**

Well I think in order to identify lessons you have to have a sense of what happened, how did it happen, why did it happen, was the judgment at the time given what was known, properly based and appropriately made or not and if not why not? If so how did it work well, how did it work if it was inappropriate. We do have to come to conclusions about those elements. I would say though that the point that we want to emphasize is that our purpose in seeking those conclusions is not in order to affix blame. Our purpose is to identify lessons and if in the course of doing it, it’s inevitable that you have judgements about what is good and what is less good. That’s just a part of the process of the Committee's work. We will have to reach conclusions and we will have to come to grips with recommendations.

**Frank Jordans:**

Can I just follow up ? You are going to have to reach conclusions and you have conflicting opinions being presented to you by the people you interview. Will all of the expertise necessary to reach these conclusions come solely from the 27 remaining members of the Committee or will you be seeking further outside help in?

**Dr Harvey Fineberg:**

Well both avenues are open to us. I mean we are, as an independent Committee, we are able to make additional enquiries to seek additional expert input to search what’s already been done in the literature. We have that available to us and it will be up to the Committee on each issue to decide what of this do we want to seek additional expert input on. What of this do we feel comfortable and capable to reach our own judgment about. So it could go in both directions and it depends on the Committee's choice with the particular issue.

**Frank Jordans:**

But the final decisions will come from?

**Dr Harvey Fineberg:**

From the Committee

**Frank Jordans:**

Not from the WHO

**Dr Harvey Fineberg:**

No.  In fact this is a really important point to me.  Our job isn't to reconcile opposing views or to convey accurately per se what someone thinks.  Our job is to ultimately conclude what we believe to be correct and that's based in part on what we learn from informants on all sides of the issue and in part on what we learn from other expert input.  What we learn from the literature and from evidence including the epidemiologic data and what we conclude through our own internal deliberations.  All of that is going to come into play and ultimately it gets distilled into a set of findings, conclusions and recommendations.  So that's the job we have.  Let me come here.  We will work our way back around.

**Lisa Schlein, Voice of America:**

I know its premature to ask you what lessons you have learned, you are still in school and you are learning.

But I wonder whether there are any patterns which are emerging, you are hearing people who are fairly supportive of what has been done and also more critical of it and Im wondering if there are any big themes that have emerged, that are emerging that you think are important to continue in your enquiry?

**Dr Harvey Fineberg:**

It is premature for me even to comment even on big themes or small but I would say this - that one of the evident realities is that the perception of what happened and why and how is radically different from different vantage points in this arena of world health and influenza.  The vantage point of the responsible public officials in countries is very different from the vantage point of others who are now coming to perhaps be critical of what those individuals and the WHO did.  It's striking if you just listen to the variety of perspective.  Its very striking to hear how diverse those perspectives are.  So one of the things that I think is a challenge in this kind of an exercise is what do you ultimately believe to be the essential reality? What is it that was true and has a direct bearing on what happened without getting distracted totally by this vast diversity of opinion and perspective and thats a very big challenge for us and I think that if you listened, if you were there for the time that we heard even for these few days you can appreciate that if your work was just summarizing, if all you tried to do was summarize the views that you hear from others you would not get very far in actually coming to grips with what you think the lessons are because the lessons that individuals see are very very radically different.

**Lisa Schlein:**

Well, given the divergence of opinions and perceptions, do you think that you can ever really bring them all together to the satisfaction of most people… certainly not all of them ?

**Dr Harvey Fineberg:**

Actually I doubt that.  I mean *[laughter]* I think that our job can't be to, you know, reconcile everybody's views.  That's not our job.  Our job is to apply our own best judgement and we have a diversity in our Committee of backgrounds from all countries of the world.  It's a marvellous group and we are really going to have our work cut out for us to see where the Committee comes down but that's our job and everybody who is on the Committee comes to it with the spirit of an open mind, we are trying to look at the evidence with a genuine desire to learn and in an honest exchange and an opportunity to try to ultimately distill what we come to believe are the most important realities and that's a big job. Yes. I will come back here.

**Unknown journalist:**

Firstly just to follow up on what John said earlier. It would be great to have the documentation available to us.

**Dr Harvey Fineberg:**

Sooner rather than later.

**Unknown Journalist:**

Yes because our resources are limited and we can't have someone sitting there the whole time and it opens up the process, it really does make it transparent if everything is available. The second thing is maybe to follow up on what Lisa was saying. What have you found most striking in what people have been telling you in the sense that I assume some of this you didn't already know or maybe you are surprised to hear people saying it out loud but what are the points that you found so far to be maybe something we should be keeping in mind or that you found striking?

**Dr Harvey Fineberg:**

Well there are many many issues but lets just take one example. The issue about characterizing the pandemic. How do you characterize a pandemic? We actually if some of you were here I know at the first meeting, already this was evident as its going to be an issue. There is a lot of controversy about whether or not WHO altered a definition of pandemic over time. There are some who are adamant that it did and there are others who explained repeatedly it did not. This is an instance in which I think our Committee at the minimum has to come to understand why do people believe it did or did not change and what was done and what was done in describing the pandemic consistent with the intent was of the people who were setting the definition. Now this question is related to the relationship of severity to spread and the severity question is a really tricky one. Now the one thing we heard that I thought was interesting on this question was from Dr Kraus if you remember from Germany and his observation was that severity is very important, spread is very important. He had in mind a proposal that I want to look at in more detail. This is one of the things I am eager to see in the follow up but his notion was that the global assessment should be what he called a risk assessment which is really about risk of spread and he wanted a threat assessment which would include severity to be done on a national level. That was interesting because if you remember when we talked even last time about the challenge of incorporating severity into spread with spread in a characterization is the variety of severity that there can be at the same time. One country, it's very severe, another country it's less severe. Even within a country, county A and county C are very different etc. So I found that very interesting as a, let me say, its a third way, you know the third way incorporates severity leave it out or do it in some interesting georgraphic way. So thats the kind of fresh thinking that I hope the Committee will examine and try to take on board, try to reflect on, come back to our conclusions about how this definitional question evolved and also how one could do a better job going forward. So that would be lesson identified and direction ahead. So that's one example that I would say was something that I would say advanced in at least our ability to come to grips with it in the course of these presentations over the last couple of days.

**Lisa Schlein, Voice of America:**

On this question. Do you expect a new definition of the pandemic to emerge ?

**Unknown journalist:**

Thats a very good question.

**Dr Harvey Fineberg:**

It's a very good question. Do I expect the, well a new definition to emerge from our Committee? I think our Committee is going to have to opine about the characterization, I won't call it definition, characterization of pandemic. Now whether what it does is just reinforce what already is, it's not new, saying on balance this is good or its something new and if new what is it going to be - we will see. But I would say that our Committee, as part of our effort has got to come to grips with that question. Yes, I will give you one more follow up and then we come here.

**Unknown journalist:**

Just to understand, you said that this is the type of fresh thinking that you are looking for. Are you also looking at whether or not there was fresh thinking in the drawing up of the pandemics. I mean in a sense of what actually, what thought process actually went into drawing up these rules and whether that process… I mean how far to the origins are you going to examine or are you just looking at the end product of the actual guidelines themselves?

**Dr Harvey Fineberg:**

No the Committee does want to understand how use of characterization evolved over time. That is part of this. Did it change and into what ways? We do want to look at that definitely. Yes.

**Laura MacInnis, Reuters:**

……I wanted to ask you about one of your projects. ……*[unclear]* my impression is that public health is fast changing situation and there could be new threats that may emerge, lessons would be useful to know before May 2011. I mean how are you sort of dealing with that question?

**Dr Harvey Fineberg:**

If something happens that calls on the application of the International Health Regulations prior to the appearance of our Report it won’t have the benefit of our Report; it’s as simple as that but I know a year might seem like a long time in the sense that something could happen in January that we wished we had done this but it could also happen in January 2012 and so I would say that we are better off trying to do it with reasonable confidence and thoroughness than we are to try to do a slapdash hasty assessment. I think there could be an argument that this is too short a time to really get to the depths of lessons and I would accept that as a valid point of view as well as I accept the notion that we wish we would have it done by November rather than by May of next year.

The timing I think is reasonable given the scope and the density of the issues, the complexity of the questions, the amount of information to absorb, the number of individuals that we want to get information from so all of that comes into play with the timing of it. And my hope is that from the moment it appears, it will be helpful for things to come after but I cant expect it will be helpful to anything that comes up before.

**Laura MacInnis:**

Do you have any sort of reporting to WHO of preliminary findings ?

**Dr Harvey Fineberg:**

The format or the form of the Report is actually specified in the International Health Regulations. In form this Committee will present its Report to the Director-General of WHO for transmission to the World Health Assembly. The Director-General has assured the Committee that her intent is to transmit the Report unaltered which is sensible. However she will also have the opportunity and indeed I think the expectation that she would provide her comment at the same time to the Assembly. So the formal routing of this Report will be the Committee's complete Report then submitted to the Director-General for tansmission to the World Health Assembly.

**Laura MacInnis:**

But before the Report is complete there will be no communication….for instance a really important lesson.

**Dr Harvey Fineberg:**

That’s correct.

**Unclear female:**

*[Unclear…]*

**Dr Harvey Fineberg:**

Well it's difficult for everyone to be at every meeting. Let me say this. We are very fortunate to have as many as 25 of our Committee at the meeting I believe. It's a terrific group but its a big commitment from people to come to all of these meetings, especially now we are adding additional meetings so I'm very appreciative. The two who were not here at this meeting were here at the first meeting. Two who were here at this meeting were not at the first meeting so you know people have to catch up they have to review the materials and the minutes and we try to make sure everybody is thoroughly informed but we do the best we can.

**Female journalist:**

The practical resume is not a resume for Dr McKenzie and Evans

Its just that…. *[unclear]*.

**Dr Harvey Fineberg:**

No, no no nothing like that. Its simply time availability. The two individuals that you mention, Dr McKenzie and Dr Evans withdrew from the Committee so they are no longer members.

**Female journalist:**

Actually I have a question on that particular point last week during the parliamentary association of the Council of Europe. Flynn said that there were actually 6 numbers of the IHR Committee that were on the Emergency Committee for the pandemic preview and that two of them were I forget, McKenzie..and that there were four others still on the IHR Committee. Is that true and is there anything that's going to be done about it ?

**Dr Harvey Fineberg:**

It's definitely not true if you are talking about current members of the Emergency Committee. There is at least one member that I'm aware in the past had been a member of the Emergency Committee but thats kind of irrelevant to the effort to review decisions made after the time she was a member.

**Female journalist:**

So the emergency committee membership is actually changing.

**Dr Harvey Finneberg:**

Oh it does evolve sure but the emergency committee is to a task. So if you were asked to come to be on the emergency committee to respond to SARS you are dismissed at the end of the emergency, your names are then public. The members are identified after the Committee is disbanded – that's my understanding of the WHO practice. So for any previous committee service it would be a matter of public record.

**Female journalist:**

But members of this  particular committee their names are released or they are held.

**Dr Harvey Fineberg:**

No once this Committee is dismissed they will be made public if its according to usual practice.

**Female journalist:**

Yes I understand but you said that this particular emergency committee on the 2009 pandemic that the members of that committee itself are evolving and ….

**Dr Harvey Fineberg:**

No I didn't mean to say that.  I apologize if I left that impression.  What I meant to say is that different emergency committees may have overlapping membership.  There is no rule to prohibit the Director-General from asking the same person who served on emergency committee X to service on emergency committee Y but each emergency committee as I understand it is convened for the purpose of responding to the given emergency.  Once that given emergency has abated the Committee is disbanded and the names are then revealed.

**Kaitlin Mara, Intellectual Property Watch:**

That was also my understanding but my understanding of what Paul Flynn was saying during the Committee…..was there…  *[unclear]*

**Dr Harvey Fineberg:**

That most definitely is correct.  No.

Let me make sure I understand to be sure.  You are saying that 6 members of our Committee are simultaneously members of the Emergency Committee for the 2009 H1N1 pandemic.

**Kaitlin Mara:**

That's my understanding of what Paul Flynn said.

**Dr Harvey Fineberg:**

That assertion is untrue.

**Kaitlin Mara:**

Ok. Thank you.

**Male journalist:**

McKenzie and Evans were

**Dr Harvey Fineberg:**

They were.  *[Unclear….]*

Now let me just say all members of the Review Committee as I understand it were recommended by someone but our Committee is appointed by the Director-General.

**Male jounalist:**

It's just that someone raised the problem with secrecy saying that if members of the Emergency Committee were vulnerable to undue influence through publication of their names then what about you people.  That means then that you're vulnerable to undue influence also.  Why are you not and if you are vulerable why are your names published.  How do you conciliate this ? *[laughter]*

**Dr Harvey Fineberg:**

Well I don't consider us vulnerable to influence.

**Male journalist:**

Well why are these people particularly vulnerable then ?

**Dr Harvey Fineberg:**

That I can't answer.  I think that all I can say is that my understanding of the current policy about Committee's other than mine is that they have been attempting to protect the integrity of the Committee by cloaking its membership in secrecy during the time that it was established.

**Male journalist:**

But not the SARS Committee?

**Dr Harvey Fineberg:**

To the best of my knowledge thats correct.

**Male journalist:**

So the emergency committee has no protection.

**Dr Harvey Fineberg:**

Well its different in the protection.

**Female journalist:**

Just to clarify. When the names will be known, when the pandemic will be….or next WHA.

**Dr Harvey Fineberg:**

No I think. Again this is something where other officials here could respond with greater authority so please just take this as my understanding because it's not my responsibility. I believe that once an emergency committee is disbanded, that is once the emergency is declared concluded at that time the membership is made public. It doesn't await the next World Health Assembly. I could look to my colleagues, is that correct ? I think thats generally correct. Please….

**Male journalist:**

Concerning the Committee from 27 to 29 June what was seen as a conflict of interest. If you actually look at the list of authors of the pandemic preparedness plan … *[unclear]* there are 8 authors who are on the list of authors are also a member of your / correct me but about a third, why is there no conflict of interest there ?

**Dr Harvey Fineberg:**

Well for a lot of reasons. Let me say about conflict of interest generally and then come to this question specifically. You know with conflict of interest what you are trying to identify is where an individual has a financial or other interest in the outcome of the deliberations which would potentially be affected by the result.

Now most of the time when you talk about conflict of interest you are talking about financial interests that an individual has or could be affected by the outcome. In general in my view a potential involvement can rise to one of three levels.

It could be so tangential and so indirect as to not require any notice. So for example,let us say that I, 14 years ago gave a talk at a particular meeting and received an honorarium at that time from the sponsors and it turned out that the sponsors were supported by a set of companies one of whom was a vaccine manufacturer. Now I made that as hypothetical, thats not true by the way I hasten to add. But suppose it were. I would say that would not rise to the level of noticeability. It just doesnt qualify.

There is another level at which you would say well there are experiences, responsibilities, financial interactions that you may have had that warrant disclosure because a reasonable person could wonder whether your view was affected by that past experience. And here for example or that current reality, I will give you an example which is correct.

In the Organization in which I work my own salary is unrelated to specific support that comes in. We try to in fact insulate the earnings of our senior officers so that we do not take any personal honorarium for any outside activity whether its on profit or non profit it doesnt matter and our own set salary doesnt depend on any of that coming or not coming its irrelevant but the Organization may be supported in some of its activities from companies that may in turn have a bearing on some activity like they may be a drug maker or a vaccine manufacturer. Now you could say well thats pretty remote to you but you know the companies support an activity thats in your Organization it doesn't have any direct relationship to you but it is a current activity and it is about a company that is you know being studied here so in my judgment I would say that that rises to more than, its not that its not worth noticing but its at the level of disclosure. You ought to make sure that that's known.

Now I would say when it comes to prior involvement of a professional character like involvement in the preparation of a plan that is not the direct subject of your study but is related to it ; so for example many of the members of our Committee in their national responsibilities were involved in policy decision making or execution related to flu whether they contributed to a global plan, a national plan, whether they were responsible for administration policy, whether they carried out the word in general I would say that also rises to a level where disclosure would be the proper course.

Now, let me just finish this and then Frank I will come back to you.

There is another level at which if you had a current active involvement of a financial nature it might require either accusal or ultimately withdrawal. If you were directly the object thats being studied or you were taking money as a part of the payroll or you were a major stockholder in a company that is currently stands to benefit or lose by what is said well thats a conflict of interest that might require you to withdraw or at least in the case of some involvement you might have to recuse yourself from certain discussions. So my personal view is that involvement such as well they participated in a plan or they actually managed the immunization programme or they were involved in some other way by and large may rise to a level where disclosure would be indicated but it does not rise to a level in my judgment that would indicate recusal or withdrawal. Frank.

**Frank Jordans, AP:**

On the issue of conflict of interest I wonder how proactive the Committee is in asking not its own members just that those involved in the decision making process that led to the definition of pandemic and various other things about their potential conflicts of interest such as you mentioned stockholdings. I mean you dont need to be a major stockholder to benefit if the shares in LaRoche go up 25%- 40% as they did over the past year whether there is a pandemic or not. Thats another question. Are you asking those kinds of questions of the people you speak to?

**Dr Harvey Fineberg:**

What we are doing, it's more than that. The Committee does expect to examine certain materials that are confidential within the World Health Organization incuding some materials about the memberships of the undivulged organizations and their conflict of interest disclosures. We will take a look at that but we are not asking each person who is testifying or giving us information about it routinely. We are trying to judge what they say but we haven't gone to ask them in every instance whether they are stockholders. I dont know if the Chief Epidemiologist of Mexico has stock in any of the companies. If you were there you heard the Committee. I don't know the answer to than.

**Frank Jordans:**

So that information would only reach you if it was publicized for other purposes, through other channels for that individual.

**Dr Harvey Fineberg:**

Then that would be in a way what we gain from that individual isn't really dependent on knowing as much about his personal holdings because we are not judging his decisions so much as we want to learn from him what they did and why. So if he was a stockholder, it's not really that central to our understanding at the same time part of our concern is about dealing with the accusations of influence by pharmaceutical companies on the decisions which is an accusation that has been made. Well you would like to know what possible routes there are for that to have actually happened. Were there any channels by which that could have occured and this is a channel so you would like to investigate that.

Well I think anyone who has not asked a question yet and who would like to.

**Male journalist**

*[Unclear]*

I'm wondering if you have any plan to examine……if there was any potential influence from the people who didn't want the Committee to declare something. Many people are talking about and actually I think there were some who didn't want the Director-General to declare a pandemic in the very early stage so do you have any specific plan to examine and their risk assessment.

**Dr Harvey Fineberg:**

Thats a really interesting question. It's a little bit like looking for why things did not happen even though some might have wanted it to happen a different way. Not directly will we be examining that point. I think the departure for us will be more what did happen and why rather than the motives of someone who wanted something else to happen but did not occur but it's an interesting angle on the story I would agree.

**Male journalist:**

Coming back to the trail is your enquiry to look at besides the possible conflict of interest or interests in other pharmaceutical .

Like the travel industry in SARS there were travel alerts and in this case there were argumments across the cuff about travel bans to countries…..and also given that one of the questions on the Emergency Committee is a senior scientist at AK which is a global umbrella body for the aviation industry, we are going to be following the trails on that and also looking at how the agency operated in the Avian and SARS cases, how to see the patterns of operation in 3 different crisis in the space of 5 or 6 years.

**Dr Harvey Fineberg:**

I think its a very interesting set of suggestions which I take on board.  We have not specifically talked about that thus far.  One of the things that's very useful in looking at the IHR is of course trying to see how it played out in different instances and those that you mention are very good comparative instances which I take your point on the travel industry as equally valid to the drug industry.  Its even larger than pharmaceutical thats right.  Many more players however.  Yes.

**Male journalist:**

Coming back to the conflict of interest.  You stated your own case that your salary is outside of the realm of any influence at the same time your Organization takes money from pharmaceutical companies is that correct ?

**Dr Harvey Fineberg:**

Yes.

**Robert James Parsons:**

Well doesn't that immediately put you under pressure because they can put pressure and you would say, we will pull the plug on your Organization if you don't shape up?  I mean you are in a siutation where you are vulnerable.  It's not like you are drawing your money from an endowment which is handled by a banking house or whatever.  Perhaps a significant amount of your money is coming from pharmaceutical company or companies that can tell the board of directors of your Organization or even come to you directly.  If you want to have a job here you have to have an Organization, if you want an Organization you need our money and if you want our money you need to go easy on us.

Wouldn't that put you in a class of 3 rather than a class of 2.

**Dr Harvey Fineberg:**

Yes, well, first I was very taken with your idea of endowment.  I like that.  *[Laughter]*

So I would like to come back to that as soon as we finish.  But everything is proportional of course.  Now if it were the case that I would claim look I have an independent salary but it turns out that 40% of the enterprise is supported by two drug companies well that would raise a different kind of question.  If it's, you know, .3% of the total then that puts it in a totally different category.

**Robert James Parsons:**

So what is it… 39.5% ?

**Dr Harvey Fineberg:**

It's much closer to .3 than 30 I can tell you that.

**Unidentified male journalist:**

So it’s less than 1%.

**Dr Harvey Fineberg:**

I wouldn’t even, I just said I don’t want to say exactly what it is, but I can tell you this in our Organization of the total programme budget roughly half, closer to 55 or 60% is from public sources – that’s Government. Roughly all but about 4% of the rest is from non-profit foundations, so not from companies. The remainder is from miscellaneous contributions of membership and other donors which are not corporate and that very tiny amount of precious endowment income and then there is a remainder which I would be confident is considerably less than 1% but I dont want to state with certainly what it is but its a fraction. To give you another idea, the work that we do at the Institute of Medicine is largely about building these kinds of consensus activities. I can tell you that when we have a concensus conference or a committee that we formulate we exclude funding for that purpose from any entity that has a commercial interest in the outcome so zero dollars go to any of those.

We have another set of activities that we call forums. The forums are intended to be discussion groups openly exchanging ideas about a topic. For example, they typically include representatives from industry from Government from academia from the public and sometimes from other organizations depending on the topic. One of the forums that we have is a forum on new drug development. That particular forum which does not produce reports, does not make recommendations is an opportunity to exchange ideas, I’m quite confident does have support from pharmaceutical companies, so thats about where it comes in. Does that give you a proportionality?

**Male journalist:**

I can accept that.

I was wondering again on another commercial link if you will be looking into it.? One of the critical points in the run up to the pandemic I think was a change in the swine flu to completely drop any reference, pressure put at least in some Governments by industry who felt that their commercial interests were being threatened or undermined by the use of swine flu. Will you be looking into the pattern of decision making how that went from Governments to three or four multilateral agencies who simultaneously on the same day changed their definition?

**Dr Harvey Fineberg:**

Its’ a really interesting point. It’s not a major issue for us the labelling. What I remember about the…..

**Male journalist:**

It just shows a pattern.

**Dr Harvey Fineberg:**

It’s an interesting point but I remember extraordinary actions. Like do you remember that there were pork bans, I mean bans on pork exports or imports you know which is about as relevant to stopping the spread of influenza as fountain pens.  You know it has nothing whatsoever to do with it but the label does make a difference apparently. I think it was experiences like that that may have been related to the choices of how to label this thing and not stigmatize.  You know they used to give the flues always were characterized by the city that it was first detected.  You have heard of the Hong Kong flu epidemic, others you know the 1918 was called the Spanish flu, that great pandemic.  It had nothing to do with Spain actually as it turned out.  So I think there is an effort to try to align the label with the, let’s say implications of the label but I don’t frankly put too much stock in it myself.  Your point though it might have lessons about influence on decisions in organizations is interesting I hadn’t thought about it.  Any other questions?

**John Zarocostas:**

The two dates when Dr Evans and Professor McKenzie -  when did they submit the letters of resignation to you?   Was it on the same day, or how many weeks apart ?

**Dr Harvey Fineberg:**

To the best of my recollection their original communications were electronic and those came in May and I believe it was May 20 and 21.

Well, thank you all very much.

*Tape ends*

# Transcript of virtual press conference with Dr Margaret Chan, Director-General, World Health Organization and Dr Keiji Fukuda, Special Adviser to the Director-General on Pandemic Influenza

*10 August 2010*

**Gregory Härtl, WHO spokesperson**: Good afternoon and welcome to this virtual press briefing of the World Health Organization taking place from Hong Kong where Dr Margaret Chan will be giving you a briefing on the pandemic H1N1 situation following an Emergency Committee meeting this morning. Also in a studio here in Geneva, we have Dr Keiji Fukuda, the special advisor to Dr Chan for pandemic influenza. My name is Gregory Härtl; I am moderating this press conference and I will now turn over to Dr Chan to make an opening statement. We will follow that opening statement by questions from journalists. We anticipate that the press conference as a whole will last approximately 45 minutes. Dr Chan, over to you, please.

**Dr Margaret Chan, Director-General, World Health Organization**: Thanks, Gregory. The world is no longer in phase 6 of influenza pandemic alert. We are now moving into the post-pandemic period. The new H1N1 virus has largely run its course. These are the views of members of the Emergency Committee, which was convened earlier today by teleconference. The committee based its assessment on the global situation, as well as reports from several countries that are now experiencing influenza. I fully agree with the committee's advice.

As we enter the post-pandemic period, this does not mean that the H1N1 virus has gone away. Based on experience with past pandemics, we expect the H1N1 virus to take on the behaviour of a seasonal influenza virus and continue to circulate for some years to come.

In the post-pandemic period, localized outbreaks of different magnitudes may show significant levels of H1N1 transmission. This is the situation we are observing right now in New Zealand and may see elsewhere. In fact, the actions of health authorities in New Zealand, and also in India, in terms of vigilance, quick detection and treatment and recommended vaccination provide a model of how other countries may need to respond in the immediate post-pandemic period.

Globally, the levels and patterns of H1N1 transmission now being seen differ significantly from what was observed during the pandemic. Out-of-season outbreaks are no longer being reported in either the northern or the southern hemisphere. In influenza outbreaks, including those primarily caused by the H1N1 virus, show an intensity similar to that seen during seasonal epidemics.

During the pandemic the H1N1 virus crowded out other influenza viruses to become the dominant virus; this is no longer the case. Many countries are reporting a mix of influenza viruses, again as is typically seen during seasonal epidemics.

Recently published studies indicate that 20% to 40% of populations in some areas have been infected by the H1N1 virus and thus have some level of protective immunity. Many countries report good vaccination coverage, especially in high risk groups, and this coverage further increases community-wide immunity.

Pandemics, like the viruses that cause them, are unpredictable. So is the immediate post-pandemic period. There will be many questions and we will have some clear answers for only some. Continued vigilance is extremely important and WHO has issued advice on recommended surveillance, vaccination and clinical management during the post-pandemic period.

Based on available evidence and experience from past pandemics, it is likely that the virus will continue to cause serious disease in younger age groups, at least in the immediate post-pandemic period. Groups identified during the pandemic as at higher risk of severe or fatal illness will probably remain at heightened risk, though hopefully the number of such cases will diminish.

In addition, a small proportion of people infected during the pandemic, including young and healthy people, develop a severe form of primary viral pneumonia that is not typically seen during seasonal epidemics and is especially difficult and demanding to treat. It is not known whether this pattern will change during the post-pandemic period, further emphasizing the need for vigilance.

As I said, pandemics are unpredictable and prone to deliver surprises. No two pandemics are ever alike. This pandemic has turned out to be much more fortunate than what we feared a little over a year ago. This time around we have been aided by pure good luck; the virus did not mutate during the pandemic to a more lethal form, widespread resistance to oseltamivir did not develop. The vaccine proved to be a good match with the circulating viruses and showed an excellent safety profile, thanks to expansive preparedness and support from the international community.

Even countries with very weak health systems were able to detect cases and report them promptly. Had things gone wrong in any of these areas, we would be in a very different situation today. I'm happy to answer your questions.

**Gregory Härtl**: Dr Chan, thank you very much for the opening statement. Before we move to questions, just a couple of housekeeping items for journalists online. Remember that afterwards there will be an audio file and a written transcript of this press briefing posted on the WHO website, which is www.who.int. In addition, the video from this press conference is being fed out now via the EBU. Finally, to those journalists who would like to ask a question, please dial 01 on your keypad to enter the queue.

Our first question is from Jonathan Lynn of Reuters in Geneva. Go ahead please.

**Stephanie Nebehay, Reuters**: Oh, hello, it's Reuters in Geneva. It's Stephanie Nebehay. I just wanted to ask Dr Chan, are you still convinced that you made the right call in June of 2009 to declare the pandemic, in view of the heavy criticism that followed. And also, regarding today's decision, could you spell out for us the implications for countries holding stockpiles of vaccine and antivirals please? Thank you.

**Dr Margaret Chan**: Thank you for those questions. Now, when WHO announced the pandemic on 11th June, we followed exactly the epidemiological and virological criteria as agreed by experts of the world. And this is a true pandemic and that was the right call, and that was the decision and the recommendation of the Emergency Committee, which I agree.

Now, on your second point, you raise about the stockpiles. As we know – and I mentioned a little earlier – the H1N1 2009 virus is still a good match with the vaccines and it is still sensitive to oseltamivir . So they would continue to be useful. And WHO strongly recommends where vaccines are available, high risk groups should be immunized and because vaccine is the best and most cost-effective intervention for this H1N1 pandemic.

**Gregory Härtl**: Thank you very much. Again, before we go to the next question, may I remind journalists to dial 01 on their keypad if they wish to ask a question? The next question is from Frank Jordans of Associated Press in Geneva. Go head, Frank, please.

**Frank Jordans, Associated Press**: Good afternoon, Dr Chan. Two questions. Several countries started scaling back their H1N1 efforts some months ago, yet WHO held back on downgrading the pandemic phase until now. Why did they take so long? And secondly, do you know how much money WHO received specifically to deal with H1N1 over the past year and what it was spent on?

**Dr Margaret Chan**: Okay, I can answer the first question. Perhaps I will ask Dr Keiji Fukuda to see exactly how much funds WHO has received from our development partners and countries to support the H1N1 effort, which of course includes deployment of vaccines and antivirals to countries in the developing world.

Now, your question is about... Yes, indeed, what you said is correct. Many countries in the northern hemisphere in fact scaled back on their public health response to the H1N1 virus. This is the right action to be taken because for countries, especially in the temperate zone in the northern hemisphere, the worst was over. But having said that, the World Health Organization has a duty to monitor the global situation and that is precisely what we are doing, and the meeting this morning by the Emergency Committee members, we showed them the global situation, but with special emphasis reporting to them the epidemiological and the virological situations in countries in the southern hemisphere, including some countries in the tropics.

Now, all in all, we are seeing clear signals and evidence pointing to the fact that the world is now – and I'm talking about it at the global level – the world is transitioning out of the pandemic into the post-pandemic period. And you asked an excellent question: what are some of those things that we were looking for all these weeks. First and foremost, we are looking for whether or not there would be out-of-season outbreaks, as we saw last year in both northern and southern hemispheres. Some people call it summer outbreaks. Now this year, this time around, we did not see that in the northern hemisphere and we did not see it in the southern hemisphere.

Now, the second point is we noticed that in countries with H1N1 transmission, the level of intensity is now moving back to a pattern similar to the seasonal influenza pattern. The third thing we observed in all these countries that we have been getting good data, there is no longer a dominance of the H1N1 virus as we saw last year. We are seeing a mixed virus pattern. By that we mean we see H1N1 virus; we also see the H3N2 and we also see Influenza B virus. And so these are some indications.

But, last but not least, another important point is that we are seeing some level of community-wide immunity, either due to natural infection by the H1N1 or due to passive immunity by vaccination. But again, the level of community-wide immunity differs in different countries depending on of course how many people were affected in the first wave. As reported in some studies now, 20% to 40% of the population were infected and in some countries where the immunization by pandemic vaccine is high, you will see that the community-wide level of immunity would be higher than countries that have a lower uptake of vaccine.

So I hope I have given you some indications of the signals or the evidence that we were monitoring and observing, and presented to the Emergency Committee this morning. And the members unanimously agreed that the world is transitioning into the post-pandemic period.

**Gregory Härtl**: Dr Chan, thank you very much. I will hand over now to Dr Fukuda to answer the second part of the question.

**Dr Keiji Fukuda, Special Adviser to the Director-General on Pandemic Influenza**: Frank, WHO basically received assistance in two main ways. One was in the form of donated supplies which came from countries and from some companies, and these included things such as vaccines, antiviral drugs and the accessories needed to administer. And then, in addition, WHO directly received some funding to help in its efforts to address the pandemic. And so in terms of money, WHO received in the order of approximately $170 million since the beginning of the pandemic. In terms of the supplies, I don't have a monetary figure for that and so we would have to get back to you on that, but those are approximate figures. Thank you.

**Gregory Härtl**: Okay, Dr Fukuda, thank you for that additional information. Once again, journalists wishing to ask questions should dial 01 to enter the queue. The next question comes from Hong Kong. Go ahead, please. It seems that Hong Kong might have fallen away, or are you there Hong Kong? Hello. Okay, shall we try to move on to the next question? Any other journalists wishing to ask a question, please dial 01 to enter the queue. I believe we now have Radio Television Hong Kong online. Go ahead, please.

**Hong Kong Radio Television**: I invite you to answer my question in Cantonese. Dr Chan?

**Dr Margaret Chan**: I would refer to the moderator.

**Gregory Härtl**: If we could perhaps leave a couple of Cantonese questions until the end, we might be able to accommodate those. But for the moment we would like questions in English only, please. Radio Television Hong Kong, would you like to ask your question in English?

**Hong Kong Radio Television**: Because I'm rushing for the newscast, is it possible to arrange it now?

**Gregory Härtl**: Yes, please, go ahead now.

**Hong Kong Radio Television**: Thank you very much. [Cantonese]

**Dr Margaret Chan**: [Cantonese]

**Gregory Härtl**: Dr Chan, thank you for that answer, and if we could impose on you please to repeat even perhaps in a shorter modified version the answer in English for the rest of our journalists. Dr Chan?

**Dr Margaret Chan**: Yes, the question basically covered two aspects: why did WHO make the announcement that we are now moving into post-pandemic period now. That answer I covered earlier on in English. And the second question is whether or not the H1N1 pandemic vaccine is still effective. And the answer is WHO continues to recommend the use of both the monovalent H1N1 vaccine, or the trivalent seasonal influenza vaccine where the H1N1 is one of the components.

Now, vaccine is still the most cost-effective and it is very effective and also the safety profile is good. So we would continue to encourage countries where vaccines are available to immunize particularly high risk groups.

**Gregory Härtl**: Thank you very much, Dr Chan. Again, to remind journalists, if you wish to ask a question to dia 01 on your keypad and also to remind you that there will be both an audio file and a written transcript of this press briefing available on the WHO website shortly after this VPC is over.  The WHO website is www.who.int.  So are there any additional questions from journalists online?  Okay.

**Jules Caron**:  Hello.

**Gregory Härtl**:    Hello, Jules Caron, I believe you're online.

**Jules Caron**:  Okay, thank you.  I have two questions, please.  I would like to know, between phase 6 and post-pandemic, what exactly does it mean?  What is the WHO doing now that it does, didn't do before?  What should national authorities be doing now that they weren't doing before?  And my second question is: the WHO still has about 15 million vaccines which need to be delivered, mostly to Third World countries, not to mention there were 12 million vaccines delivered to Bangladesh ten days ago; what does this say about the WHO's response to this pandemic that those at the highest risk of infection received their vaccine after the threat of the pandemic has abated?  Thank you.

**Dr Margaret Chan**:  What I'll do is I'll take your second question and I'll ask Dr Keiji Fukuda to deal with the first question.  Now, you're correct; the WHO in collaboration with Mr Ban Ki-moon, the Secretary General, UN, core countries and the industry in the name of global solidarity and fairness that, you know, certain amount of vaccines should be delivered to WHO and through WHO for deployment to countries that do not have the vaccines.  Now, by the time we finished the vaccine deployment exercise, which will come to an end in, pretty soon, we would have deployed vaccines to a total of 83 countries and these are countries who requested WHO for assistance for vaccines and we are doing this as part of our commitment to global solidarity.

Now, you are absolutely correct; some of the vaccines did not really arrive as early as we would like it.  And this is not only the situation for the donated vaccines to WHO; this is also happening in some countries.  And, as you recall, the virus, the seed virus that were used for making the vaccine at first did not grow too well in eggs and that sort of delayed it, the production timelines.  But, all in all, the world has benefited from the use of pandemic vaccines.  Now, as I said earlier, the vaccine is still a very good match with the circulating H1N1 2009 virus and it is our recommendation that, you know, the vaccine should continue to be used.  And it is no surprise that, you know, we should expect, like in previous pandemics, to see the 2009 H1N1 virus continue to circulate in countries and cause outbreaks.  And as to the magnitude of the outbreaks, it is very difficult to predict and the best method to protect is really to take the vaccine.  Thank you.  Over to you, Keiji.

**Dr Keiji Fukuda**:  Thank you, DG.  There are a couple of important points to make related to the second question about the differences between being in the pandemic and the current period.  I think that the first one is that this action simply notifies countries that we are transitioning out of a period in which we have seen unusual patterns related to influenza, back to a period in which we see influenza patterns more typical of seasonal influenza.  However, during this period one of the things which we are strongly emphasizing to countries is that it's important to continue monitoring and (stay) alert for unusual circumstances related to disease – this could indicate still ongoing severity of this virus – and also to be on the watch for any changes in viruses.

So one action is to continue with surveillance.  A second action that we are recommending is that it is important to continue with control efforts.  We have noted still that in a number of countries there is still intense activity related to this H1N1 virus.  Although globally we see that patterns are returning, in some countries we see that activity remains relatively intense and so we strongly support the ongoing efforts to control these outbreaks.  Now, overall, however, we expect that as we move out of the pandemic into the more seasonal period that the intensity for some of the surveillance and some of the actions which were considered during the pandemic period will no longer have to be considered by national health authorities.  Thank you.

**Gregory Härtl** l:  Dr Fukuda, thank you very much for those additional remarks.  The next question is from April from National Public Radio in the United States.  Go ahead, please.  April, are you online and able to ask a question?

**April, National Public Radio**: I'm here.

**Gregory Härtl**:  Go ahead, please.

**April, National Public Radio**:  I can hear you.

**Gregory Härtl**:  We can hear you now.  Thank you very much.  Go ahead.

**April, National Public Radio**:  Okay.  Dr Chan, was it a mistake for countries to destroy the vaccine then, if you're saying it still works?  A lot of countries have started destruction.

**Dr Margaret Chan**:  April, you ask a very good question.  Let me put it this way: the countries, you know, certainly when vaccines which still have a valid shelf life should continue to be used.  But, however, vaccines that have a shelf life that has expired should be destroyed in keeping with best practice.  Thank you.

**Gregory Härtl**: …much. The next question is from Gabriela Sotomayor of Notimex.  Go ahead, please.

**Gabriela Sotomayor, Notimex**:  But my answer, my question has been answered.  Thank you very much.

**Gregory Härtl**: …very much, Gabriela.  We then go to the next question, which is from Betsy McCaughey of The Wall Street Journal.  Betsy, go ahead, please.

**Betsy McCaughey, Wall Street Journal**:  Hi, thanks very much.  Dr Chan and Dr Fukuda, I wondered if you could answer a couple questions about the response in New Zealand and in India.  Dr Chan, you mentioned that they're a model for how countries should respond in the post pandemic period, so I just wondered if you could elaborate on what steps you're referring to specifically?  And my second question was in that light, in that vein; what other countries you may be watching closely where activity, H1N1 activity is intense right now?

**Dr Margaret Chan**:  Thank you, Betsy, for those questions.  WHO, along with our countries, will continue to monitor the situation in the post pandemic period.  It is important that the surveillance of disease must be maintained for several reasons.  Number one: we need to see whether or not the way forward this H1N1 virus will turn a very difficult course, meaning may cause more lethal disease – that has to be watched.  Another thing is we need to watch whether or not, you know, the oseltamivir  resistance is becoming a problem.  Although we do see some resistance globally, but this is not at the level that we are of concern because oseltamivir  is still effective, but that has to be monitored.

Now, another important thing is, while we are monitoring globally what's happening our countries should not forget, as we are speaking, we are in phase 3 with the H5N1, the avian influenza.  So, all in all, I mean, disease surveillance for respiratory disease must be maintained to see whether or not this H1N1 will become milder or more severe.  Does it, is it going to change in terms of the high-risk group?  Is it going to change in terms of the clinical pattern?  And don't forget, you know, lurking in the background we have H5N1 which is still causing sporadic cases in a large number of countries in South East Asia and also in Middle East, so these are things we need to do.

Now, why did I say, you know, India and also New Zealand are good?  Because they maintain the vigilance at a time when many countries, you know, I'm afraid to say, have become quite complacent and so that’s why they are good models because you can never be sure with influenza virus. So their heightened level of disease surveillance, prompt response, mounting appropriate public health interventions, including the use of vaccine for populations and high risk groups is exactly what we would encourage countries to do so. Thank you, Betsy.

**Gregory Härtl**: Okay. Dr Chan, thank you very much for that. The next question is from Stefan Bussard of Le Temps newspaper here in Switzerland. Go ahead, Mr Bussard, please.

**Stéphane Bussard, Le Temps**: Yes, Dr Chan, given the experience and evidence you’ve gathered over the last year will you change anything in the guidelines to respond to a new pandemic that might break out in the future? Thank you.

**Dr Margaret Chan**: This is an excellent question. I mean, there is always lessons to be learnt from every pandemic and this is no exception. And, if you recall, WHO, you know, will encourage countries, while we are now moving out of the pandemic into the post pandemic period, one of the things countries can do now is to review their pandemic preparedness response and see what are some of the lessons that can be learned at the national level or sub national level so that they are better prepared next time. Now, globally WHO will be working with partners and of course will be, you know, providing support to the review committee who is reviewing the performance of the organization, as well as on how the International Health Regulations 2005 as a legal instrument – how does it work in coordinating the actions of the world. So there will be very valuable lessons to be learned so that these lessons can feed back into the, you know, next pandemic planning. Thank you.

**Gregory Härtl**: Okay, thank you very much. Before we move on to the next question, to remind journalists that we have little over ten minutes left of program for questions, so we’ll try to fit in as many questions as we can in that time. The next question is from Lisa Schlein of Voice of America. Lisa, go ahead, please.

**Lisa Schlein, Voice of America**: Thanks, Gregory. Hello, Dr Chan. I was wondering how you’re feeling now that you have announced essentially that we’re finished with the pandemic or at least moving into a post pandemic phase? Are you feeling good? Are you feeling tired? Are you relieved? And then another couple of little questions and that is: what is the latest death figure from H1N1 and do you expect that figure to rise in the post pandemic period when you have a chance to really investigate some of the information that you weren’t able to do earlier? And lastly, following on Stéphane's question: the WHO was accused of hyping the pandemic and I’m wondering whether this might pose problems for you in the future if as and when a new pandemic arises?

**Dr Margaret Chan**: Lisa, can you repeat the third question? You know, I didn’t hear it too well.

**Lisa Schlein**: The third question was, the WHO was accused by a number of people of having hyped the H1N1 virus, the pandemic, and I was wondering whether this might pose problems for you in the future, in terms of getting countries to actually respond to a new pandemic, should it arise?

**Dr Margaret Chan**: Okay. I would like to respond to the first and the last question, and also invite Dr Keiji Fukuda to comment on the figures of the… the death figures, and how the world should work in the future to look at, you know, the estimates, in terms of, you know, the excess mortality caused by this H1N1 pandemic.

Lisa, you asked a very good question. How do I feel? Do I feel tired? Do I feel happy? Do I feel…? I feel both, because, you know, this is… has been a long year of work. Hard work, not just by colleagues in WHO, but by public health officials worldwide. And having said that, we are also, you know, mindful of the fact that we need to continue to maintain our vigilance, and not be complacent, so there is going to be a lot of work to be done in the future, and one important thing is to review lessons learned, and how the world, collectively, can be better prepared for the next pandemic.

Now, your question about, you know, WHO's… Did we overreact? The answer was no, we did not. WHO has been very consistent with its messages, even at the outset and subsequent announcement, or, you know, our web update, we mentioned, and we brought to the world's attention, we are dealing with a pandemic of moderate severity, and most people, majority of them, will recover from the disease, and many people will recover without treatment. However, you know, of one or two things of big concern to the global community is this special predisposition of this virus to cause severe disease in young adults, especially young adults with no underlying or previous medical condition. And it causes severe disease in pregnant women. That is unusual, compared to seasonal influenza, and that's the kind of things we don't want to see. I think we have struck the right balance. This is a moderate pandemic, and of course the death figures would not be immediately available. It would take some years to get the precise estimate, then, you know, history and records will show whether or not the estimate by the world's experts is on the mark.

Now, over to you, Keiji.

**Dr Keiji Fukuda**: Thank you, DG. Lisa, just to add a couple of points to what the Director-General said, the current estimates for, or the current number of laboratory confirmed deaths is about 18,500 worldwide, and so what this means is that for each of those persons who died, there was specific laboratory testing in confirmation that they died from the H1N1 pandemic infection. So as you probably know, this is a very unusual situation for so many people to be individually tested, when they die, for influenza. So we expect, as Dr Chan said, that over the next few years the more usual ways of counting deaths from this pandemic will be applied, and then we'll have a picture about what the more accurate numbers of deaths will be. So we consider this current number to be the minimum number of deaths, and we expect that over the next few years, as we use more usual methods for estimating the deaths, that the numbers will be higher. But of course we don't know what they are right now. Thank you.

**Gregory Härtl**: Dr Chan, Dr Fukuda, thank you. The next question is from Sharon Kirkey of Postmedia, in Canada. Go ahead please.

**Sharon Kirkey, Postmedia News**: Thank you. Thank you for taking my call. Dr Chan, I just want to confirm that essentially today what you've done is declared an end to this swine flu pandemic. And my second question concerns vaccines. Countries like Canada still have remaining vaccines from last year, but the vaccine approved for the 2010 and 2011 protects against three strains of vaccine including H3N2, so what should we be doing in countries like Canada, should we be first, you know, using what we've got from the stockpiles of last year, or should we just be moving directly to this season's flu vaccine?

**Dr Margaret Chan**: (Sharon), thank you for that question. That's important. As we said earlier, you know, the… a monovalent H1N1 vaccine, if it is still valid, within the validity of the shelf life, it can be used. Now, then the, of course the seasonal influenza vaccine, which is a trivalent vaccine, including the H1N1 component, can also be used. It depends on availability of the country.

Now, in some places, you know, we know that some countries use the monovalent vaccine for children, targeting at young children, because I mean, in certain… we read that certain products, the seasonal influenza vaccine is subject to further investigation of the reason, young children, after receiving that seasonal influenza vaccine, developed a febrile convulsion. Now, it is not of the magnitude of something that is of big concern, but to play safe that may be one of the options how countries like Canada can consider to use the monovalent H1N1 vaccine. But let me reassure you, (Sharon), Canada is a very solid and, you know, robust country, in terms of competence in public health, and I have full confidence in the national authorities in terms of their recommendation and guidance to their people.

**Gregory Härtl**:Thank you very much. Sharon, did you want to re-pose your first question, are you still on the line?

**Sharon Kirkey**: Yes, I'm still on the line. If you could just, if we could just confirm that essentially what you're announcing today is an end to the H1N1 flu pandemic?

**Dr Margaret Chan**: Yes, phase 6, you know, we're no longer in phase 6 of the pandemic, and we, you know, the, of course the Emergency Committee experts also agree that, you know, the public health emergency of international concern no longer apply. So yes, in simple sentence, yes, the answer is.

**Gregory Härtl**:Thank you very much, Dr Chan. Next question is from Jamil Chade, from here in Geneva. Go ahead, Jamil.

**Jamil Chade**: Hello, Dr Chan. A quick question also on this issue of level 6, 5, etc. Where would we put now the virus? Is it phase 3, as H5N1? Or where is it, basically? And secondly, when you talk about the revision of the regulations, are you talking also about making it public, the names and the people that are actually taking part on the committee that took this decision today? Thank you.

**Dr Margaret Chan**: I didn't… Jamil, I didn't hear the second question too clearly. On the first question, yes, I mean, you mention H5N1, and as I said earlier, this is still something we need to maintain our vigilance. H5N1 is still causing sporadic diseases in human, and the case fatality rate is reaching, you know, as high as 60%, so we should not let our guards down for this new virus. But we are in phase 3 for the H5 N1.

Now, the second question, can you repeat it, about the IHR to…? Are you referring to the IHR 2005?

**Jamil Chade**: Well, basically my question is whether the names of the people in the committee that took the decision today, will they be, from now on, publicized, or they will still be kept as a secret?

**Dr Margaret Chan**: I think, you know, Jamil, the names will be released today, later.

**Gregory Härtl**:Thank you very much, Dr Chan. The last question we believe is from Miriam Falco of CNN, if she has been able to get back online. Miriam Falco, are you there? Okay, unfortunately she's dropped off, so the last question is from Matthew Lee, of Kyoto News. Go ahead, Mr Lee, please.

**Matthew Lee, Kyodo**: Hello, Dr Chan?

**Dr Margaret Chan**: Mr Lee.

**Matthew Lee**: Yes. I just want to know if you think there is any lessons specifically learned during this H1N1 pandemic? And also, if this pandemic come back again, will the level of severity be considered as one of the deciding factor when you decide on what phase of alert level should it be?

**Dr Margaret Chan**: Thank you for that question. There are actually many lessons learned, and, but you know, let me mention a couple that I feel are very important.

And number one, for WHO, as well as for many of my countries, my Member States in the organization, communication is a big challenge. You know, now we need to adapt the way we do communication and learn how to work with social media and social network. And that is again, one thing we need to have a better handle on.

Now, the second thing is the pandemic preparedness guideline was planned, discussed and decided by the world’s experts, under the threat of the H5N1 avian influenza virus, and that gave them the sense that collectively we should plan for the worst and hope for the best.

Now, the lessons we learned from this H1N1 pandemic is perhaps we need more flexibility in our future pandemic planning. We need to be able to have a best case scenario, an intermediate scenario, and a worst case scenario to allow, you know, flexibility and adjustment as we evolve, or as we track the evolution of the pandemic. I'm sure, I mean, that worldwide there is wide agreement amongst experts that we need to review the phases, including the severity, and also to have more flexibility.

**Gregory Härtl**: Dr Chan, Dr Fukuda, thank you very much for having been with us here today. Journalists, thank you for having joined us. Before I let you go, just to remind you that shortly on the WHO website will be available an audio file and a written transcript of this briefing. Once again, thank you for having joined us today. Goodbye.

# Transcript of press briefing with
# Dr Harvey Fineberg, Chair,
# International Health Regulations Review Committee
# 29 September 2010

**Speaker key**

HF Professor Harvey Fineberg
MF Member of the floor

HF Well, thank you all and the only one who has not introduced himself is our cameraman who will remain unseen but always welcome. It's a pleasure to see you all here. As you know we have just concluded three days of meeting. This is the third meeting of the IHR Review Committee. This meeting was organised in two parts similarly to the second meeting. The first part of the meeting was plenary sessions in which we had the opportunity to interview individuals representing a variety of organizations and interested parties. I'll review that in a moment. And the second part of our meeting was what we describe as deliberative sessions. This is the part where the committee alone carries on our discussions and the development of the ideas and content organization of the report that ultimately will be released.

The plenary sessions are open to representatives of state parties, the constituents of the World Health Assembly who are invited, also UN organizations and other organizations, non governmental organizations that have a special relationship to the World Health Organization and as some of you I hope yourself took advantage but it has been our custom in the work of this committee, the plenary sessions are also open to members of the press as auditors. I don't know if any of you were able to sit in on any part of this meeting; if not that will help in what I should describe. Shall I assume we have not; that you have not heard what went on?

MF Many were covering judicial issues in the Human Rights Council.

HF Ah, so there's other events going on in Geneva even as we speak? All right, well, I will take that into account in our discussion. The plenary sessions this time included further interviews with representatives from national authorities. These are the state representatives, the national focal point, the individuals with the responsibility of communication, co-ordination from the point of view of the individual states. We heard also from representatives of industry and other organizations that are involved in response or preparedness for pandemics such as the International Air Transport Association and today or rather yesterday we heard from representatives of Sanofi Pasteur, one of the major vaccine producing companies who participated in the WHO vaccine distribution programme.

Over the course of these several meetings we've also heard from other industry representatives, from Hoffman La Roche, from Novartis, from Glaxo. We've heard from our representatives of media in Europe and particularly also from critics of the WHO including representatives of the Council of Europe, the Cochrane Collaborative, some who have been writing in criticism of one or another aspect such as the BMJ editor who spoke with us at our last meeting.

I would say though, most of the time of the plenary session, the largest single chunk of time this session was dedicated to hearing directly from the WHO secretariat. This is the group who played the key leadership responsibilities within the WHO for oversight of the management of the pandemic and indeed administration of the International Health Regulations.

I think you're all aware that our committee really has a dual charge. We're constituted under the terms of the International Health Regulations of 2005 which called for a review after five years of the performance of the International Health Regulations. We're also constituted specifically to review the performance and activities in connection with the H1N1 pandemic. Importantly this pandemic, the H1N1 pandemic was the first incidence under the implemented rules of the IHR of 2005 which went into effect legally in 2007. The first instance where there was a declared public health emergency of international concern. This is a special classification under the terms of the International Health Regulations, and it's under that authority that the World Health Organization operated to carry out its programmes and activity under H1N1 and so these two are closely enough related that it was deemed appropriate to look at both simultaneously and that in turn affects the approach that the committee is taking in preparing our report.

We have to consider both issues related to the performance of the International Health Regulations and issues related to performance and concern on the H1N1 pandemic specifically and our goal will be to cover both, to show how they're inter related and to draw lessons from each for the future. This is our overall mission; the overall mandate to our committee from the beginning has been to examine what happened for the purpose of drawing lessons for the future. What has emerged in thinking of the committee in terms of how we're organising our work thus far is really five major lines of organization and development: one is essentially setting this context explaining the backdrop of the history of the regulations that are principles of communicable disease, where influenza as a problem fits and then specifically the 2009 outbreak.

Secondly, we're working on understanding exactly what happened in the early stage, the outbreak up through its assessment that preceded the ability to respond to it so this early phase assessment's very critical. Third, we're looking at the response and the response has many, many parts but the idea will be to understand how all these parts worked, what didn't work well, what did work well, what we can see that might be improved in the ability to respond to the epidemic.

We're going to focus more specifically on the range of functions of the IHR. If you go through the International Health Regulations themselves, it's actually a rather readable document. It's in typical legalise but it's not that lengthy. It is an international treaty. It has the force of law on all the signatories and it has, if one analyses it, a number of distinct functions, quite a part… some connected to this pandemic, some more general but understanding how they worked, how well they have served to improve preparedness capability, response capacity in countries around the world. This is an important part of our mandate so we'll be looking specifically also at the IHR. And finally and I think of special interest to this group we are going to look specifically at the issue of communication. The communication issues permeate the entire process. They arise from the very beginning. In fact they precede the beginning, the groundwork laid in communication, it's partly a matter of the processes of communication, it's largely a question of quality of communication, it's a matter of the relationships and accomplishing the goals of the communicator and achieving the desired understanding and beliefs and behaviour on the part of the audiences that are the targets of the communication. And the communication is of course a two-way street. One has to be a listener as well as a speaker for communication to be successful. And we are looking at all of these aspects of communication in connection with the total experience here so by the time we have gotten our arms around this whole problem we will have understood the context, the early stage, the response stage, the functions of the IHR and the role of communication. That's the general scope of what we're now working towards.

From a process point of view, the committee plans to extend the discussions, the deliberative discussions of this meeting in early November. Our custom really since the last meeting we have had opportunity to carry on some telephonic interactions. They've been very useful in organising our work and making some progress. Meeting in person helps a great deal. Most of the committee is actually staying along informally for another day or two here in Geneva to continue the development work. That will continue by electronic means and telephonic consultations over the next month. We'll try to gather again in person in deliberative session in early November and our goal is to have a draft that is able for us to review and try to finalise in early January and we do plan a final plenary gathering of all the countries in early January and we'll see how far we are along at that point.

We have a goal of submitting our final report and that would have to include the translation of it as you know into the official languages of the WHO UN system and a response from the Director-General who is the direct recipient of our report. That would have to be all accomplished in advance of the meeting of the World Health Assembly in May of 2011 which is when we expect the report to be released in effect.

So that's the plan, that's the status of where we are and I'd be very happy to respond to any questions that you would like to raise. The floor is open. I think if you push the microphone. Mine doesn't have a button so I'm assuming I'm all right.

MF Yours is on all the time.

HF Mine is on all the time. All right.

MF Did you have any… are you starting to get a picture of certain elements of the response to the pandemic through this process, especially during this third meeting? Are there any particular features that come out that surprise you?

HF I would say one of the things that is, not exactly surprising but revealing, is that the principles at the WHO, the secretariat are very eager to tell their story. They are as eager to tell their story as I would say some of the critics that we have heard from have been eager to make sure we understood the nature of the shortcomings and different aspects and I think part of what's coming out from their side is two things: one is the challenge of decisions and actions under uncertainty in real time where you don't know exactly what will follow and you are facing uncertainties at every level and the press events pushing along are all going on with many things happening simultaneously so one of the key themes that's emerging from this is the force of uncertainty and the second is complexity, the complexity of what they were trying to deal with, the number of things they had to in a way invent for the first time despite all the preparations, despite all the preparedness, the nature of the discussions, for example, with the range of industry on response to the pandemic. And one interesting contrast I would say was between the preparations for managing the response with respect to antivirals as contrasted with the management of response for vaccines because in the case of antivirals the drugs could be produced. They were already available, approved, on the market. They could be distributed stationed in pre-positioning for further distribution. It was a relatively simple but still a complicated task but logistically manageable task of distribution.

In the case of vaccine, it's a totally different picture, you don't have the vaccine at the outset, you have to create the vaccine. You have to get companies to agree to participate or countries to agree to donate. There, in the end, were dozens of countries that were donating and scores of countries that were receiving. Companies had different views about what they would be willing to do and interested in doing so that was a very, very different challenge and in a way one has to think how much of it could be prepared and how much was of necessity because of the nature of the intervention new so one of the… I would say one of the big lessons that we gathered was this sense of complexity from the WHO.

And the third point I would say, and it came through to me very, very clearly in the statement of the Director-General, which I believe is now posted already on the web and it's worth looking at I think if you want to get a feeling of the tone and a sense that she's bringing to this process but I was impressed with the willingness to listen and eagerness to hear what the committee would have to say about the assessment of what happened so that there was a reinforcement to the members of the committee who were devoting a substantial amount of time to this effort that what they produce will have an audience. I won't say that it will necessarily be adopted but it reinforced the value of the time that individuals on the committee are putting in.

So those were some of the key impressions I would say that we're particularly from the… from talking with secretariat. Other things that we got that were reinforcing again everyone from this, involved in this had come at it from their own perspective and very, very few people really had a vision of the whole, of the totality. You know, you have a certain perspective from the air transport industry which is perfectly legitimate but is different than the perspective of the state authorities, different from the perspective of the region of WHO, different from the perspective of the public health officials and similarly with industry and with the other groups that we've heard, they've each told that important side of the story and helped enrich our understanding and I think part of the job of our committee will be making a coherent whole out of all of these perspectives. Yes?

MF I was wondering if you could elaborate on the differences between what you mentioned with the antivirals and the phase with the vaccines from your interventions with industry. We understand the commercial confidentiality but what reading did you get, where did things get tangled up between the WHO and industry players in the preparation of the vaccine, the delivery, etc?

HF Well, I think the first point is that we haven't yet enumerated all of the ways that you run into trouble with this vaccine distribution. It has come up even from the beginning as a source of some criticism. For example when we heard from some donor countries, they raised the question why has our donation not been out there, what's been happening, what's taken so long? When we heard from recipient countries they were concerned in some instances that it was getting less and later than what they had desired or needed so you had on those two sides a perception and a sense of disappointment that there was not more and faster. So between the time that you have a knowledge of a vaccine getting started and the ultimate distribution there's just a myriad of things that can interfere and go wrong. We're just starting to sort that, go through all that but clearly just to indicate a few, the negotiations with the donor countries have to each be individualised and you have to, depending on where their sources are coming from, what they're willing to pre-commit to, how firm that commitment will be and depending on what happens in the pandemic, then you have this separate negotiations which is all of the companies. They're each individual and then you have the questions of when exactly, where do you get a vaccine that hasn't been approved in the recipient country? How do you get that there? So do you have to go through all of the approval authorities when it hasn't yet been tested in those countries? How do you overcome that and then is there capability in the recipient country to administer this in a short time, you know, the whole question about implementation on the ground in the final stage so all of these can act as impediments to a successful distribution.

If you just contrast that for a moment with the story of the antivirals; drugs are very familiar. It's a pill you take once. People… every country there's distribution systems for drugs. These drugs are approved. So there's just a whole array of non-obstacles relative to the case of the vaccine so that's what we're trying to both enumerate and identify in concrete form and use to illustrate some of the challenges that were faced and then to think most critically okay, what did we learn that we could do better next time? Are we going to be in the same situation the next time, and that's the task we have. Yes?

MF Two questions: the first is your…from what I understand you're going to look at the… part of what you're going to look at is going to involve whether the response was appropriate at an epidemiological level but when you're examining this will you also look at the whether it was reasonable at an economic level? I think a lot of people would want to know how much do the public and private sector spend on for this pandemic. There's no reliable study out there yet. How much vaccines are rotting away in warehouses, etc so will you be looking at whether the economic response was appropriate or not? And the second question is regarding the methodology by which you will reach your conclusions: you speak of several stories from different agents which tend to reinforce themselves. Shall we assume that you will be discarding the outliers from this great narrative? How will the report take into account that maybe some individuals have an entirely different story to tell?

HF Well, let me take the two questions: I think it's beyond the capacity and scope of this review to conduct an original in-depth economic analysis. This is not something that we're going to be in a position to do but I am aware of several that are underway including some in Europe, some in the Americas and perhaps more and what we will try to do is to take advantage of the analytic work that is being done and use that as part of our assessment and understanding but to take the larger point, certainly a judgement about the wisdom, the correctness of the judgement that was made or judgements really that were made have to have an economic element so I accept the premise very, very well, just that if you, as you ask the question will we have an original and complete assessment of the cost, the answer is not by our committee. We'll try to take advantage of what others will do.

Now on the other point that you raise, the committee has a responsibility to make its own judgement about the merit and validity of the information we hear from all sources and it’s not just what we have gained of course in the testimony. We have an immense amount of documentation that we have accessible to us, available to us. We have of course the entire literature and what may be referred to as the fugitive literature, the stories along the way. We have a history of the media coverage for example that is available to us. So the committee will be deliberating based on the information it has gleaned from our testimony plus the documentation and other sources of information that are available to us. It’s hard to know generically what we will accept and/or reject and I think it’s entirely imaginable that a committee would reject what is a mainstream view and accept an outlier view or reject the outlier view and accept a mainstream view. That’s the judgement that we have to elicit from the committee’s honest assessment and I wouldn’t want to say which is going to be ultimately the committee’s choice. And of course there are many, many varieties of position on some of the key issues. Yes, please? I will work our way around if I may.

MF [Unclear] there was a discussion on the definition of the pandemic, if there are [unclear]?

HF Yes, we covered this point in our discussion with the secretariat and we also understand ourselves, very, very firmly that this is a critical element of our review. There’s a debate about what is the proper definition, what elements should go into the definition. There is debate about the definition actually employed at different points in time and how and in what ways the WHO conveyed information about working definitions, if not legal definitions. There are questions about the implications of the definition for action and the connection between if you will the assessment of a pandemic or potential pandemic, the risk assessment part and the management or response to the pandemic, the so-called risk management part so how are those connected, how should they be connected?

So the committee is very firmly focussed on this question as a part of what it is attending to. So the issue of definition is very important and as you know from even from our past discussions, those of you who were present in the last discussion, the question at a basic level of severity as well as spread is an important component of that question of definition but that’s not the only part that we have to examine. Yes, please? I’ll just work… go around and please push the microphone button, thank you.

MF So I wanted to ask whether following up on definition issue has your committee been able to find a definition? When you talk about the definition are you referring to a text, written, published that one can cite, quote and if we all quoted it it would be the same and unchanging or are you referring to a general concept because there is no definition? Can you kind of explain, please?

HF What I would say between the definition and no definition is rather many definitions. There are multiple ways people have elected to define and describe what they mean by a pandemic and I would say that part of the difficulty is that the small duplicity has led to confusion and at least induced very different understandings of what the meaning of the field reality is today and so I think that what we are going to try to accomplish is to explain what was both in the minds and on the paper or in the electronic form at different times, how these had implications for thinking and action at different times and what the recommendations would be for the future in terms at the minimum of clarity, consistency and practicality which are attributes you would like to have in a definition.

Now finally I would add that when you begin to look at the responses to, or potential responses to a pandemic it also may come to be seen that you want different definitions for different purposes, that is you want to understand different aspects of the field reality for different types of decisions or actions that you may want to take and that is also something the committee will have to consider so I would pose the characteristic a little differently than none or one, I would say many right now. Yes, please?

MF You've heard from a great number of people already in groups and so on: have you heard from the right mix of actors and are there… is everyone being heard that wants to be heard?

HF From the outset we have made very open invitations to any individuals, groups or others to please convey to us their advice, their papers, their comments, their suggestions and so we have received from a number of professional and non-professional sources input to the work of the committee. We have had papers shared by writers of those papers. We've had presentations sent to us. We have had references to other work that people think have a bearing. We have received from some of the state parties very interesting and thoughtful assessments not only of their own situation but of their relationship to WHO and the role of the WHO. We've had an opportunity in the course of these three meetings thus far to hear from a good range of representation, from the public and private sectors, from government, non-government sectors, from the global to the local. We've heard from industry representatives. We've heard from professional associations of different kinds.

I would be very eager to make sure that we can definitively answer that question yes and indeed I would say that if we have omitted an explicit invitation from any group that any of you feels would be informative I would actually appreciate knowing it because there's still time but we have been very insistent from the outset that we want the best advice that we can get. We feel we have an obligation to try to absorb the best thinking that's out there and if we have the benefit of that we think it's likely to improve our final product so that's working hard toward that goal, thank you.

MF I apologise if you answered these before I got here. Two questions: the first is that one thing I keep hearing from you today and then also it was in Dr Jen's opening statement was thank goodness this was a mild pandemic because we just didn't get the vaccines where they needed to go in time and I'm wondering if, as the committee is reviewing what happened, if you're centering in on any sort of plan for making the vaccine distribution and implementation process go faster and in particular I'm curious, there's elsewhere in the WHO negotiations on going for a pandemic preparedness framework and one of the things being discussed is a material transfer agreement that would be standard for the transfer of vaccine and virus related materials so would that speed the process or would that not. And then the second question is one of the things that critics of the process have been complaining about for a long time is this sort of mysteriousness around the members of the Emergency Committee who declared the pandemic and if now they were released on the 10th of August, you have the names; I wonder if that has changed any of the discussions within the IHR Review, has there been anything brought to light you think is important?

HF On the first question one of the very interesting parallel activities is a group that is a working group of the World Health Assembly that is looking at the question of virus exchange and benefits, the sharing of information and of bio material and the benefits that ought to follow from that and what is the correct balance of advantage and reward for those parts of the world where the virus may appear and those parts of the world where the vaccines and other drugs may be produced. Sometimes those are similar and sometimes those are dissimilar.

In most pandemics they have been different and it's most of the influenza pandemics have arisen in densely populated, relatively poor countries, not in this particular instance but that could well occur again and then the issue will come up, well, if you provide the virus material as a nation what is the proper positioning that you have in relation to the vaccines that will be produced because that virus has been available?

Now this working group has been deliberating for many months, more than a year on this and I believe they are… they may be coming towards some conclusions on their work. They are very eager to take advantage of the thinking of our committee as we are eager to know what their thinking is and we had at the second meeting actually a presentation from the co-chairs of that committee which was very helpful so I think that on this issue there is a lot of parallel activity going forward and there will be more than just our committee's report that will have to deal with these questions. Now…

MF But you haven't come up with anything that you think [inaudible] yet?

HF Well, I wouldn't say that we have come up with anything that is a solution yet. I would say we have not come up yet with a recommended solution. That we have not done yet to be clear. But let me answer the second part of your question and then I'll come on… I think the second part of your question was on the Emergency Committee and the names that are revealed and has that affected our thinking. We of course knew that the Emergency Committee was confidential until such time as it was revealed and the question of the advisability of that in the future is clearly one of the issues that our committee is going to have an opinion about so we are fully engaged with that.

There are pros and cons that have been articulated. The fundamental pro in favour of confidentiality is the idea of protecting the members of that committee from undue influence from either national or commercial sources and it's not just influenza cases, I mean you have to think back to the SARS case and the intensity of national interests around SARS and concerns about what it would mean for different countries economically and otherwise so there's an argument on that side and then the argument on the side of revealing the names is about transparency and assuring a public that individuals who've played a part in recommending these actions indeed are doing so without influence by commercial or other sources so that's… that is a… that is definitely one of the issues we have to come to grips with and draw our own conclusions and recommendations so we're very much aware of that.

MF But this time around have you drawn any conclusions?

HF You mean about this particular committee?

MF Because you now know the names, you did not the last time?

HF We haven't as a group yet looked at the individuals to answer the question: was this group well constituted if that's what you mean, was it fairly constituted, was it correctly constituted: we have not yet done that. Yes?

MF I'm back. Sorry. Come back to your deliberations with member states and in particular their assessment on their relationship with the WHO. I presume some of these interventions were also from the focal points. What were the lessons, what did you learn that could improve things in the future? Where did the member states sharpen the pencil on the secretariat and where do they think the secretariat was up in the job?

HF Yes, thank you for the point especially the distinction between member states and national focal points. They're both nationally based but we've heard from both. We've heard from ministries more broadly and we've certainly interviewed and met with and heard from a number of the national focal points. The national focal points are the individuals designated in each country with the responsibility for liaison and action with respect to the International Health Regulations. That's their role. And most of what we have heard from the national focal points who have testified, we heard from a number also at this meeting, by and large has reinforced the value of having the ready channel of communication and the clear designation of responsibility.

We have not heard, to the best of my knowledge, from any national focal point or responsible individual who has offered a negative assessment of the value of that designation and role.

Now we have heard about suggestions for improvement. We have heard about ways that communication could be improved for example. We have heard about from some questioning whether the legal authority given to the WHO is sufficient to deal with some let us say deviations from recommended policy. I'll give you the prime example that has come up is the early assessment at the WHO that border closing would have no role in significantly altering the course of the epidemic. Nevertheless a number of countries took action to close or to limit entry in their countries and of course some spoke very candidly to us. We heard from a couple who said, well, you know, in a country you have a political need to demonstrate to your public that you are doing something about this threat and so it may be that the thermometers measuring temperature at a distance at an airport have no value from the point of view of the literal control of the epidemic but they may have a lot of value of reassurance to a public that is comforted to see, well, at least the authorities are doing something so we had this discussion. It was very informative, very candid and I think very helpful to us.

MF What about the member states?

HF The member states, yes. I would say…

MF The policy level.

HF The policy level: one of the kinds of points that some member states raised had to do with this again the question of donation and receipt of the… of vaccine. That was an issue, that was a source of at least criticism from some of the member states that we heard. Some framed it more as questions they wanted us to look into, others more as a criticism. Some of the member states found certain negotiations more tedious than they would have liked, more difficult communication than they would have felt was ideal so that was another type of comment that we've heard from member states.

One of the things that I would say though as an overall comment from the majority of the member states and particularly the countries that you would say have received assistance from the regional or central offices of WHO, most of their assessments by and large have been positive. There's the problems of the lateness of the vaccine but by and large we're not hearing a lot of sharp criticism from those quarters. The most critical views that we have heard I would say have come more from the developed parts of the world, particularly from Europe, at least overall that is what I would say so far.

MF Criticisms?

HF	Of criticisms, yes, mainly.

MF	On the topic of criticism, I guess when I think about criticism, you know, criticism's expected for any governmental agency: whenever EPA is considering regulations there's criticism or there's criticism to pass regulations, there's criticism for FDA for approving drugs, there's criticism for not approving drugs. Is there anything different about the criticism this time and, you know, what do you make of the criticism and some, I'm just referring to the recent speech in Hong Kong, Michael Osterholm, he sees the criticism as part of an anti-science movement so what do you and the committee feel? Has that been discussed and how's it best to interpret the criticism? Your mention of Osterholm reminds me we also heard from Osterholm actually as one of the witnesses. I didn't mention it. We had… this was in a group of… among experts let's say but now…

MF	[Inaudible.]

HF	No, he's an American actually. The name is not… I think it's actually… is Osterholm Swedish, Danish? Perhaps Danish but he's Scandinavian I think more but in any case he's American and he's based in Minnesota so that Minnesota is… we have a lot of Norwegian immigrants in Minnesota so I have no idea if that has anything to do with it but in any case, to come to your real question, we are interested in all criticism as a committee and not be, not with the judgement is it similar or different to other criticism; we're interested in one key question: how does this criticism help us to do better in the future. And I will say that even ultimately where the committee may as a group come to say we don't agree with that criticism, the fact of a criticism that is widely shared or widely spoken is itself a message about the process. And so you have to take criticism seriously at least at that level and then you have to make a judgement about the substance of the criticism and the legitimacy of it and in all cases we're looking at those questions with the pure intent of what do we learn that could be more successful in the future. That's our laser focus as we look at all of the criticisms so we're not making judgements is it the usual stuff or exceptional stuff; is it outrageous or is it logical; we're asking how does it bear on a greater success of coping with the next emergency pandemic and that's the question the committee is asking. Yes, you want to follow up on that?

MF	Yes, one of my… my understanding of some of the nature of the criticism is that there is fundamental research and some of the science is not sound and these… that assertion is something that goes back to before the pandemic, before April 2009 and so how is the committee addressing the fundamental scientific issues that are raised by those criticism?

HF	Give me an example because there's people who say flu doesn't exist, really and so what you mean?

MF	What have you heard?

HF Well, within the people we've heard from [overtalking].

MF And [unclear] I think [inaudible].

HF We did hear from all three of those actually and so they're quite different in the nature of their criticisms. I would say starting with the Cochrane collaborative ideas, they are much more critical of the science undergirding the effectiveness of interventions, period, interventions, whether it's antiviral or even vaccine, and at a public health level as distinct from individual level so that's the nature of that criticism.

I would say that when you look at the whole array of let us just call it expert view on efficacy, that that's an outlier view, that is not a mainstream position. However, it's a position that is firmly held and grounded in an interpretation of a body of evidence that is highly selected and highly refined and this gets into the whole philosophy of the Cochrane approach which is legitimate but in my mind limited so that's what we heard on that level.

The criticism from the BMJ, from the editors and what they wrote was really I would say largely focussed on the question of transparency. That was the fundamental thrust that again relating to the earlier question, that the Emergency Committee's secretiveness is contrary to the public interest and urging that that be reconsidered.

From the Council of Europe was hardly that but more fundamental about the, I will say the suggestion more than the accusation, the suggestion that there was corruption of the decision-making and advising due to commercial interest and so that was… that's quite a range of criticism, each I would say distinct, bringing a different vantage point to us and we have to take it all, and are taking it all on board. You're asking what do we make of it as yet? I'm sorry.

MF The question is for Tom Jefferson if there's only Jefferson out of those three, there are concerns that the science is, that is being employed is not correct assumptions and so the scientific assertion of disagreement so is, within the scope, I heard your opinion about that science but within the scope of the committee and its review and its report is that going to be something you're going to address or is this going to not address the scientific questions?

HF I can't answer that yet. That is to say it's up to the committee to decide to what degree we will deal with that specific aspect of the question. I would say though that it is… it represents an outlier of the scientific view and it's not a widely held position that that is the extreme position which is to say fundamentally don't use antivirals and don't use vaccine. The implication is because you haven't proved that they work by randomised control trials. That's the argument and there're many randomised control trials and writers of randomised control trials of vaccines that would take different view of their results so as I said it's a view that is grounded in a selected body of evidence that has merit to a degree in my opinion but is an outlier of the scientific view so will the committee in depth deal with that question? Probably, you know, it's a little bit of a distraction from our main responsibility because, you know, it would take us into… if I were writing it myself, you know, or if we were writing it we would make it an appendix, you know.

MF Like you did in your book?

HF For example, I mean besides… that would be the way, you know, you might want to deal with that but I wouldn't put that in the mainstream of the story. I think it would not be the main line of what we're trying to develop as an argument to prepare better for the future. How are we doing on time? Is it okay? Can we keep going? Okay, great. We'll start back… why don't we start back around in case anyone has a final question, to go round once more.

MF Considering [unclear] what happened for [unclear] lessons for the future, will this review answer the question on whether WHO's response to the pandemic was appropriate or not? That's my first question. And considering the WHO's responsible, rightly or wrongly, to the pandemic which thankfully was pretty mild, do you as a public health professional feel that the public has lost trust with the WHO's judgement on these significant issues?

HF Okay. On the first question we'd have to be much more precise about exactly what aspect of response we're talking about. There were innumerable responses and implementation of those responses and there were certainly flaws in those responses but if you target a particular decision and implementation of it and you'd say what was right about it; what was wrong about it, what do we learn from it, that's the way we're going to be thinking about this. We're not coming at the question from the beginning with a question of just making a judgement for its own sake, we're not here to praise or to decry what happened. We are going to make judgements about critical aspects and if out of that there's a let's call summary judgement that one would want to draw whether the committee wants to draw it or a reader wants to draw it from our assessment, that will be accomplished at the end but that's not our principle purpose. Our purpose again is to look at each of these elements and see what could we do better.

MF If I could follow up on that, will the committee examine whether the decision by Dr Chan to declare the H1N1 virus a pandemic was appropriate or not?

HF Yes. That I can answer yes, I do and the second question was remind me again, trust, do I worry about trust. I worry about trust every day. I, as an individual who spent a fair portion of time in public health, as a teacher and as a researcher and someone who was concerned about public health I feel that every day what we do in public health, in communication either strengthens or weakens the public trust. It doesn't stay the same. It either gets stronger or it gets weaker and there are a lot of forces to weaken public trust in public authority of all kinds, not just public health authorities. So public health is embedded in attitudes of public toward authorities, toward government, toward experts and if you look at the least, where I'm most familiar with, the US public opinion polls over decades, in general public trust has been diminishing in virtually every profession may I say including journalists so all of us who are involved in relating to the public ought to be worried every day about this and I am. Yes?

MF Two questions: the first one is more controversial to just referring back to something you just, you mentioned [inaudible] a national source, a government source and I'd like to turn it around slightly and take an international look at it and ask the question is whether you would be discussing [inaudible] and the question is does the WHO have a political view to demonstrate [inaudible] but in fact more general terms. I was wondering if that's an issue to take down?

HF Unrelated to our examination I would say it certainly does. WHO depends on the political support of the World Health Assembly in the first instance for its mandate. It depends on donor countries to get its financial support. It depends on demonstrating repeatedly that that money is well invested and used wisely so undoubtedly the WHO as an organization has a powerful interest in documenting and demonstrating that it is doing well.

MF And do you think that is something that the committee should take up to see whether or not influence on the decisions related to the [inaudible]?

HF Well, one of the beauties of an independent committee is we don't particularly care whether it helps or hurts the WHO as an organization, that is it's not our mandate or concern or worry. I would say that if I were separately advising the Director-General I would say that the best hope you have of maintaining a political confidence, public trust is to do the job the best way possible so I think there's a nice convergence in fact of interest of the WHO doing well by doing good. That is it will retain its support if it simply does a very good job and I actually don't think in the long term there's any alternative. There's no sleight of hand or means that the WHO could mobilise other than doing its job. It would persuade anyone that is worth supporting. I'm sorry, the second question about the state…

MF No, the second question was [inaudible] national political [unclear] but it's whether or not WHO… now the second question is something else. It's more simple. I was just wondering what are the gaps, what's missing from what you've been hearing so far either in terms of the committee either in [unclear] divide it into two, either in terms of their being gaps in what you have heard and would like to explore if you feel there are gaps and secondly what's outstanding on your agenda?

HF Yes, well, I would say on the question of gaps, if you look at these lines of work that I outlined earlier, in the detail there are many, many gaps. In fact we've been working hard with access to let's call them informers. These are experts or individuals in positions of knowledge or responsibility who can help fill our gap so we have at the detailed level multiple gaps. In terms of the overall assessment, where we have been really just beginning our effort is in examining an extensive library of material which includes some that are public materials but available to WHO, some that are internal WHO documentation of what they were doing at different times, the minutes of meetings and such including of the Emergency Committee for example and then some confidential materials which have been made available for examination which includes such things as the agreements with the vaccine manufacturers so where we have a lot of work to do in this next phase is immersing ourselves in that body of information to make sure we've got our arms around it. You want to direct me on that? Yes, please.

MF Yes, on this very question, have you examined any of this material especially the commercial confidential agreements between WHO and companies and also the donated materials given by companies and if you saw any delays for errors in judgement or logistical problems by the secretariat or by industry or was it a combination of both? We've heard… some of us have heard for instance that some industry groups had vaccines available from WHO but logistics was the problem at the WHO.

HF Yes, you know, this gets also to this point I was making earlier that, you know, if you talk to different groups you hear their version of the story but it is true for example, WHO didn't necessarily have all the money it needed just to ship the vaccine. How do you get it from the donor to the recipient? You had to get carriers to take it for free. No, well, how do you pay for that shipping? So, you know, that was… that sort of you think, well, gosh you would wake up in the morning, you'd know you have to pay for the shipping but then where do you get that money and in the middle of doing a hundred other things and what if no one thought about that, what if there was an assumption that the donor was going to ship it of course but what if the donor said no, here it is on the dock; take it or leave it. You know, we'll be glad to have it available and you just come get it so that was… this was one area of shocking you might say, you know, lack of full communication and preparedness so that's part of the story of this.

Now getting to your specific point on the… we haven't in depth gone into the agreement but my suspicion, and it's just a suspicion now is we'll have learned more about these problems not from the content of the final letters but from understanding a little of the process that led up to them, from looking at some of these other logistical matters and from questions of practicality. Those are more likely I think to reveal lessons about doing it better in the future but we are going to look at these…

MF Am I allowed a follow-up?

HF Yes, sure.

MF We were hearing from WHO officials, especially in the vaccine area; we were told vaccines would be available X period and then there was a delay and a delay and a delay. So was there a communications breakdown between WHO and key vaccine suppliers? Were the industry people misleading WHO or were the... was it an internal problem?

HF I'll speculate a little bit here, because we don't... we haven't nailed this down completely, but I believe that part of the difficulty was too definitive a communication about availability dates in the face of a lot of uncertainty around production and all of the things that you need to do between having the seed virus and having the actual vaccine in a immunisable form. How potent is it going to be? How effective? One dose, two dose? How much will you need? How much will the virus grow? How much antigen will you get produced in the eggs and so on. So you've got a lot of uncertainties. So it's speed... amount that would caution you against excessive definitiveness of the date when something is going to be available. So, you know, it's a little bit like when you say to someone; I'll be there at seven sharp and you're there at 7:03, you've disappointed them. But if you say; you know, I'll get there around seven and you're there by 7:10, that's fine, that's around seven. So it is partly communication and expectations of what is determined.

Now having said that, there also were some other delays that we need to look into and understand. But it was... It's partly how it was framed and partly how it was executed, I think, that are both subject to improvement. Another question. Yes? Sure.

MF Actually I have four right now.

HF Four! Oh my gosh.

MF They are quite small.

MF This is a press conference.

MF I don't know how they work.

HF It's good, it's good, we'll go as far as we can.

MF So one is a quick one, a yes or no I think.

HF Okay.

MF So will the criticism you heard of the three people... will those become public documents? The second one is; what is your understanding of the phase six definition, what impact did it have recently and there's debate about this between nature and BMJ [?], one suggesting that it didn't have an impact at all? Sort of like a foregone conclusion and others saying it had an impact. And I was wondering if your committee has also been thinking about what impact the US declaration of a National Public Health emergency has on WHOs decision making, because it proceeded chronologically if my understanding is correct.  And the last one is to get a sense... I'm trying to understand what's already going on in your committee's work; so how much time do you spend on this and other people and do you have people in your staff, like for example, like the Institute of Medicine, who work on this, prepare documents like briefings. What's the manpower and time going into all this?  I'm happy to repeat if...

HF	Do them one at a time if you wouldn't mind.

MF	So will the criticism that you heard in the second meeting...

HF	Will be public.

MF	Become public document?

*[CORRECTION TO THE FOLLOWING SECTION: transcripts or audio files of interviews done in plenary sessions of the IHR Review Committee are not posted on the WHO web site. Plenary sessions were open to public observers but WHO noted that interviews would not be transcribed for public dissemination at the outset of the sessions. Other documentation related to the committee are available on the web site at www.who.int .]*

HF	As far as I know, it's already public.  We're just to say... I don't think we heard anything from any of the three specific critics that you've named, who told us anything they haven't written and said publically many times.  So we were... we did not receive what I would call unique criticism from them, if that's...  So that's already public.

MF	But as a story you'd want... I mean they made a statement on a certain day and you want to be able to look at what they said, how they framed their open statements and things like that, but...

MF	It's online.

HF	I think it may already be.  Is it already available?  I think it is.  I think everything is on. Anything that was in our plenary sessions is available.  Okay so that... The short answer is yes.

MF	They are already public documents.
HF	The answer is already.

MF	That's the answer.

HF	Yes, okay.  Second question was...?

MF	The BMJ [unclear] debate over whether phase six...?

HF	Oh yes, did phase six matter? You know part of the difference depends on... You mean does it matter to what the course of the epidemic is, or does it matter to responses that were taken? And you know there's certainly... there were certain arrangements such as advanced purchase agreements that had built into them triggers that depended on the definition of a... or the declaration of a pandemic. So there were certain things that were triggered. Now would those things have...? Well then the argument is; well it might have been there as an agreement, but that was going to happen anyway. I mean that purchase would have gone forward regardless. I mean the United States, just to give you one example that I'm very familiar with, United States wasn't waiting for WHO to declare a global pandemic before it was doing everything it could to mobilise the vaccine. So I think that you could see where this argument is going back and forth. The committee I think has to come... Where the committee has to judge isn't you know, nature versus BMJ; that's not our problem. Our concern is; what can we say about the way epidemics are characterised in the future, that...? And what implication should it have for risk management as opposed to risk assessment, that would help clarify and avoid inappropriate or misunderstood reaction. So that's where we're going to focus. Now the third question?

MF	Well it's... you mentioned somewhere, the US Declaration.

HF	The US Declaration; I don't think... You know again you have to remember this; the pandemic was going on in different degrees in different parts of the world. And so certain countries who were early affected naturally had an earlier policy response than other countries which had not yet been affected or were just beginning to be affected. So I wouldn't say that as a declaration, as a policy question it had a direct influence. What it did is, of course mobilise a lot of action within the United States, that's totally different. But I don't... I wouldn't say that I see a basis on which it had, in that policy arena, an action or effect in WHO. And on your last question, which I do remember, because it was reminding me how much time we're spending on this; the committee is putting a great deal of time into this and indeed I would say for many, if not all members of the committee it's taking up more time than they might have understood at the very outset of accepting the obligation. We have a support staff based here in Geneva, who are dedicated to our work on the committee and have been very helpful to us. And in answer to your specific question, that's the staff on which I rely for this project. So it's not an Institute of Medicine activity. I'm here as an individual and working on this in the capacity as an individual

MF	So that's supporting WHO staff?

HF	They are based at WHO, but dedicated to us.

MF	But they are WHO staff.

HF They are employed by WHO, yes.

MF Don’t you think you need to have an arm’s length relationship with them?

HF With that staff? Well they’re not staff who were involved in the...

MF But they still work for WHO.

HF They still work for WHO, that is true. I think that, you know, we’re very aware of that, but this is going to be the committee’s report, that I can assure you. As I think every member of this committee, working on every element of this, would assure you. Well, if there are no further questions, thank you all very much for being here. One more? One more, all right.

MF Did you get...? When you say you got responses from policy makers, did you get responses from Ministers of Health to get an insight on how cabinets dealt with the Pandemic at the national level and how was the response? Because if there was one missing link, very few heads of Government or State took a proactive stance on this issue.

HF Yes, we did hear... Some of our witnesses happened to be Ministers of Health, but not of what you would say the major critics or donor countries. But most... To the best of my recollection, as I think back on the input we have received, it’s not been from a particular individual, whether minister or other, it’s been a delegation submission of the delegations here at the assembly. That’s to the best of my recollection. So as I remember looking at the...

MF But these submissions draw on... drew examples of how it was held at the cabinet level. For instance, when Dr Chan on June 11th said; pandemic, did you get any insight on how it was dealt at the cabinet level in various governments...?

HF No.

MF Given that the Ministries of Health are not necessarily the heavyweights in cabinet.

HF No, we’re not getting at that. Keep in mind, we’re... An assessment of what happened at a national level is way beyond our scope. We...

MF But that’s very important.

HF It is important, but it’s not something that we’re in a position to examine systematically around the world - what effect did this have? Now if you mean by this; what did it mean for the country response overall, when the WHO made certain declarations?  That is relevant to us, but we're not getting it out of these submissions.

MF	It could be helpful though.

HF	It could be - it could be.  Very good.  Another question?

MF	I'm sorry.

HF	All right, number five.

MF	It's on this whole Ministries of Health and early on, in May 2009 the Ministries of Health, not the majority... I didn't take a count, but I know the UK, China, Japan, these are the main probably... they were very critical of the possibility that WHO would declare a phase six. So are you tapping into that criticism and concern from those ministers or those... whoever the delegates were, to the World Health Assembly in May last year, to understand why that mattered to them?

HF	I would say we haven't specifically pursued that, but actually I would welcome your guidance on what you know about who was reacting at that early period because we could still enquire about that.

MF	It was a plenary session in the [unclear], where most of the Ministers spoke on the record in a three hour session.

HF	Yes, but I don't remember from... I... At that session we heard from many, but I don't remember China or the UK specifically.

MF	UK spoke.

HF	Did they speak?

MF	Oh yes, he was very critical of the definition.

HF	Yes, a lot of the people then... But he was critical on the question of severity, as I recall.

MF	Exactly.

HF	Yes, so it wasn't this issue.  I'd like to understand what was the positions taken at that stage and I think your point of why; it's a very good question.  Were they concerned about the triggers, were they concerned about public anxiety or rumours.  What were they worried about?

That's a... I think it would be helpful to know and it might be different in the different countries. I should look back. I don't think that China did speak though, at that meeting.

MF I think they did.

HF China also spoke?

MF Minister of Health.

MF The ones I recall immediately are UK sort of led.

MF A lot of countries jumped in - Spain.

MF Japan.

HF Yes, in May?

MF Japan I remember being one of the other countries.

HF Yes. Well you know it's a very relevant point and I think it would help me if you could identify with specificity which ones that you know had issued some sort of public statement at that stage. I would be appreciative.

MF He has a question as well.

HF Sure you have one.

MF Looking at the whole pandemic just through the phases, there was no phase one, there was no phase two. On April 27th it was phase three, on April 29th it was phase five, so it in effect had skipped a phase, and then went phase six, but there was no post-peak. There wasn't really post peak, so basically half of the phases, you know, this beautiful [unclear] pandemic [unclear] plan was ignored by the WHO. Half the phases weren't [unclear].

MF You're a little off there; there was a four.

MF Yes, it was on... But it was on the 03rd in the morning, on the 27th in the morning was the three... on the 27th at night it was the four. It's now on the 29th it was a...[unclear]

MF It was three because they were already in phase three.

MF So just as a lay... as a non... I'm not a medical... I'm not a doctor; I'm not a medical professional, but if I just look at the application of the tool you have and how it's applied, the tool is completely useless...

HF Well let's take a medical analog for a moment. If you're just measuring temperature, you know you can have a normal temperature in the morning and you can have a fever by night. And the question isn't how swiftly did they go from one phase to the next or did they skip a phase? To me the question is, first, are the definitions logical and helpful and optimal and then, did the criteria actually get met and when and with what basis. And if it turned out that the temperature just became evident in the course of that day, that's the way it is. So you know, I think the mere fact that it was jumping or skipping or condensed, that isn't per say a criticism, it's only if that mismatches to the reality.

MF Every phase comes with a certain policy response both at the WHO level and at the national level and these phases exist to, you know, give some kind of coherence to national government, especially those organising resources. So this tool which was basically to simplify... to give government sort of a plan in the case of an actual pandemic, was ignored.

HF Yes, that virus didn't cooperate, did it? I mean that's basically the problem there. You know, you have to deal with nature as it is, and the reality. And then you learn from each experience, as we're trying to and you figure out, can we adjust those in a more effective way. But I think again it's... You can criticise the logic, which is valid, you can criticise the completeness, which is a valid question, you could criticise the application and say; did they have the right evidence at the right time? But the mere fact that you move quickly or slowly, to me is not a criticism.

MF In your interventions, did you hear anything, or from anyone that most people had been prepared for years on the H5N1?

HF Oh yes.

MF Which has a higher fatality rate and that the mindset was prepared for something horrific.

HF Absolutely, this is... I would say that one of the other, I think very evident lessons from an array of the testimony is that a lot of this thinking and planning was actually predicated on a mindset grounded in H5N1 and that is... that's undeniable and it's actually quite important. So I think it's actually a very, very relevant point. It did set the framing of how people thought about flu and the virus didn't cooperate again. A different one happened to come up. Anyway, thank you all very much.

World Health Organization

# Transcript of press briefing with
# Dr Harvey Fineberg, Chair,
# International Health Regulations Review Committee
# 28 March 2011

**Speaker key**
HF  Dr Harvey Fineberg
MP  Member of the Press

HF  Yes, okay so... So I'll just say that what we had today was the fourth and the concluding plenary meeting of the review committee. That this was an opportunity for the committee to hear from member states and NGOs who are the recognised participants at the World Health Organisation, for their comments and advice based on the preview document that we distributed some weeks ago, to the member States. And the preview document represents the principle findings, conclusions and recommendations that the committee, at that time, put forward. That background document includes three principle conclusions and 15 recommendations. Can I assume that you are all familiar with it or you have seen it? So the purpose today was to give an opportunity to the member states, first and foremost, and others to give us their feedback.

I would say that we heard from, perhaps, between 12 and 20 presenters today and we've received perhaps a total of between 20 and 30 comments, either verbally or written, about the preview document. A number of the observers commented in support of one or another or all of the major ideas in the document. And so those are of great welcome to us, but they're not the ones we're focussing on now. We're looking to understand where there were questions or criticisms based on the individual states perceptions and advice to us. And now the committee's job will be to take those into account and to formulate our final report. As a general matter, I would say that the committee did its best to produce a report based on all the evidence that we had before us. That evidence consisted of extensive interviews over the last year, which many of you also witnessed, a thorough assessment of documentary evidence, written materials related to both IHR and the pandemic.

I would say that our report endeavours to be measured in both elements worthy of praise and elements worthy of criticism. And we had some of both. We wanted this report to be constructive in that it was intended to help learn lessons in a constructive way, to improvement. And we wanted it to be forward looking in laying a base for future improvements for public health emergencies and pandemics among them. Overall, I would say the comments today reinforce the major lines of our conclusions and many of the recommendations. The questions that came up were partly questions seeking clarification or more elaboration, for example, one of the recommendations that the committee offers is a recommendation about the distribution of vaccines, in balance with the availability of viruses, the so called, open-ended discussions about virus sharing and vaccine distribution. And there were questions about exactly what did the committee mean when it said that States that received donated vaccines should adopt the same principles about liability as the States that purchase vaccines. So that was a question about that.

There was a question about the recommendation that suggested the establishment of a pre-positioned line of credit, available in the case of a future emergency, exactly where should it be located, exactly why should it be at the scale that it is, those kinds of questions that came up. There was some suggestions about elements of the report, for example, one of the recommendations indicates that in accordance with each States assessment of its priorities and benefits and costs, that we urge wider use of vaccine against seasonal influenza, as a means, both of protecting the population and of extending the capacity for production in the time of a potential pandemic. One of the suggestions today, cautioned that if you have a rationale for immunisation in anything other than the protection of the population at that time, for that... against that disease, that it could, in the long term be a weakening public confidence in such recommendations.

So there was a caution in other words, that it... don't make too much of this idea that you're recommending seasonal flu vaccines simply to prepare for a pandemic production need, when in fact the recommendation could and should stand on its own, for the protection of people, year in and year out. So that's another example of the kind of suggestion that we heard. Right now, we're going to take all of this onboard, as a committee. The whole array of these several dozen suggestions and then formulate our final report. We expect that this report will be submitted for the World Health Assembly meeting in May and presented and discussed at that meeting. We hope that the report will be actionable and practical. A report that is simply on a shelf and not translated into action is not what we intend. So let me invite your questions and I look forward to trying to respond.

MP I have one question.

HF Please.

MP Your report, can it be seen as a template on how to judge future international measures taken by WHO to fight a pandemic?

HF I would even generalise it a bit more. You know, the report has a dual character. It is, on the one side, an assessment of the international health regulations and on the other side it's an assessment of the response to this pandemic. The part of the report that deals with improving the international health regulations is the part that I think will have, year-in and year-out value. Because every year we're going to have the need to call upon the kind of resources that the international health regulations establish, in surveillance, in monitoring, in communication, responding to everything from a radiation disaster in a country to natural disaster, to a future pandemic.

So those... that side of the recommendations, I think, will have literally every day value. Now when it comes to pandemic preparedness, a lot of the recommendations, for example, the whole array of priorities for research, in understanding the predictors of virulence and spread. And the other elements that we talk about, those will be of value also for seasonal influenza, not only in the case of the next pandemic. So to an extent, on both sides, of the pandemic review and the IHR review especially, I think there will be lasting and regular value of the review. And it will also prove its worth if it does manage to strengthen preparations before a next pandemic.

MP I was wondering, in the draft report the details are lacking, at least in the end and appendix on what... maybe draw some of the conclusions, for instance, that we didn't see any malpractice or any direct links between the way the policy was formulated by the secretariat and member States and any... and no direct links with a possible conflict of interest, by industry. But at the same time, we recommend the establishment of an ethical officer to oversee these events. What was the reasoning for this? And secondly, in the final report, will there be a listing of all the people who gave evidence and their submissions attached? Thank you.

HF Let me comment on the last point. We received very extensive submissions, from many sources. We also had access to some confidential documents, from within the WHO. All of the documents which are public, that is excluding those which we had access to by virtue of our special status as a review committee, we expect will be publically available, by probably electronic means. They will not be printed in the print version of our report. So that, I think, is the way it will have public access. The full report of course, will outline in much greater detail, the basis on which the conclusions and recommendations that are in this preview document come forward. And in particular, I would just comment on this question of the conflict of interests that you raised, and the recommendations. It's impossible to prove a negative. That is, you cannot prove that there was an absence of influence. What we did say, and what we have concluded is, we could find no evidence for it. We found no direct evidence from any source and we couldn't find any indirect evidence, other than assertions by some who believe it was the only plausible explanation.

We also believe that there are alternative explanations for the actions taken, that are more plausible to us and for which we have evidence that they in fact exist. I'm referring here, for example, to the power of the public health ethic, to prevent the loss of life, as one illustration. Now, when you're thinking about the future and the protection of both the integrity and the credibility of what the World Health Organisation is called upon to do, the fact that there was no evidence of malfeasance or of inappropriate influence by industry, that we could find, does not preclude, in fact, is entirely consistent with recommendations to strengthen the approach and management of conflicts of interest, by the organisation, that we do recommend. So we're recommending it more in the spirit of good practice and prevention, than as a remedy for an error in the past. So that's the basis that we make our recommendation, with respect to the ethics officer and the other aspects of disclosure, for example, and dealing with conflict of interest. Is that a response?

MP Yes.

HF Good, okay. Other questions? Yes please, go ahead.

MP	Just a follow-up question. I think you were asked some questions from the floor, about the advanced purchase pricing, but again, your report sheds no light on that. Is the final report going to provide some analysis on that aspect, which was an issue? That in earlier briefings, you highlighted, was very cumbersome and time consuming to negotiate these agreements with various providers of antivirals or vaccines. So...

HF	There are two separate issues here. I don't want to conflate. The concern about the difficulty and time consuming character of negotiations in advance, referred not to national advanced purchase agreements, but rather to the World Health Organisation's effort to put in place agreements with multiple parties, that would facilitate and enable vaccine to be delivered to less well financed countries, who could not afford to purchase it. So we did not actually, as a committee, deal with the... directly with the process of negotiating in the countries that are buying vaccines for themselves, with the companies. That was not our mandate. We were very concerned with the process of negotiation around obtaining vaccine for redistribution in the world. And that was very problematic in the pandemic. It was slow, it was difficult. Interestingly, the Director General, in her remarks at the meeting today, said that in her view it was predominantly systemic obstacles that made this a difficult task.

The obstacles of the lack of harmony around regulation of vaccines, the difficulty of dealing with liability, which is a core concern of the manufacturers and the challenge of working through things like the cold chain, which had to be in place in order for donated vaccine to serve its intended purpose. So in her remark, she was emphasising again, how much effort they put into it and how hard it was. And the committee will have to take that into account in our final report, in terms of how we express what we believe can effectively be done in the future, to be more successful in this endeavour. Because everyone recognises that it remains a very serious impediment to the world's ability to deal with a future pandemic.

MP	I'm sorry sir, my question was, I think, from the floor you were asked specifically about the advanced purchase pricing and there was one suggestion that, perhaps in the future, there is transparency in the prices.

HF	Ah, I see, yes, no that was a separate point, yes, okay.

MP	And that's not reflected in your report.

HF	No.

MP	The question of how countries negotiated contracts and what triggered them and whether they were commercially above board, or not.

HF	Yes, we didn't deal with that in our report, because the report itself, fundamentally could not deal with reviews of individual countries. This was not the extent of our capacity to examine. It was a very interesting observation however, I would add, about the lack of information about pricing. We just didn't examine it. Yes?

MP How do you explain the basic assumption that it was necessary to buy all these doses of flu vaccine when Poland bought nothing [unclear]? Poland had one of the lowest cases of flu anywhere. Haven't you taken into account that maybe this wasn't even necessary at all and what were the initial decisions based on, in the end? And then there's also the other question, which I raised with you once before, it's the whole mindset, without talking about influence direct or indirect, it's the whole mindset that pervades the collaboration that namely anything that works with the corporate sector is going to be good, so that [unclear] don't question it. And on the contrary, we tend to facilitate it and enhance these arrangements. [Unclear] at great pains to find any, sort of, serious, obvious influence and even indirect influence, yet it's an underlying assumption that's unspoken that ropes people and shapes their behaviour. Did you take any of this into account in the end? What about Poland, how do you explain that?

HF Well let me start with the fundamental question. The committee's view is that this was a real problem. That in the beginning there was great uncertainty as to how severe it would be, and that that uncertainty persisted through the time when purchase decisions had to be made. In my view, ignoring that evidence would not have been responsible as a measure to protect the public's health. Now, it's a little bit like saying; whether fire insurance was a good idea for your house. If you look back over the last year and your house did not burn down, do you then say, I was a fool for purchasing insurance?

MP Yet at the time there were serious questions about where the information was coming from and the whole... the development of the virus in Mexico, for example, and the implications of, who did this... To avoid any investigation into how they were raising their animals and how they were providing for incubation spaces for this virus.

HF Well you're now raising a completely different and important question about the origin of influenza pandemics. And indeed many new infections, in terms of their animal origin and the mixing of animals and humans. That's a separate question. Influenza is a very versatile virus. And its capacity to simultaneously infect different species, is a very unusual property in the pathogen world. And that is one of the reasons that makes it a continually dangerous pathogen, because it has this multi species capacity and because of the changeability of its viral composition. But that's a completely different question from the validity of the evidence, early on, about real outbreaks of real disease, in a number of countries. And the committee's view is that this evidence was clear and compelling. Now on the other point that you raised, which was, did the committee think about relations to industry, or what was the point that you assume...?

MP Underlying the [overtalking] which is much more difficult to identify.

HF Well the committee had no direct view of this. I mean, to give you an illustration, if vaccines were produced by non-profit or national laboratories, the committee's attitude toward vaccine would be exactly the same as if it's produced by companies that make profit. So the attitude of the committee, toward the manufacture and distribution of the vaccine had no bearing on whether it was produced by a for-profit company.

MP	Which committee?

HF	My committee.

MP	No, but I'm talking about previous to that, those who were in WHO were so orientated towards the corporate sector and their willingness to push in the direction of anything that will profit industry.

HF	I can't even comment on the premise of your question. I have no idea that that's true.

MP	I see it repeatedly, that's why I've raised the point.

HF	But what does that have to do with our review, if it is true?

MP	Because it's an underlying attitude that pushes in the direction of ordering huge doses of vaccine and perhaps neglecting to consider [unclear] information or whatever.

HF	Well...

MP	And...

HF	I still can't quite see how it's connected to what our review is trying to say. If your... If the argument is that the judgements about vaccine were premised on an underlying predisposition to help companies make a profit, we could find no evidence of this.

MP	Not to help them make a profit, simply to accept without questioning what they want.

HF	We could find no evidence of that. The judgements about the virus, the need for a vaccine, the testing of the vaccine, the distribution of the vaccine, were not unquestioned judgements that didn't try to weigh benefits and costs. They did look at risks of vaccine; they looked at efficacy of vaccine. This was not an unthinking global acceptance of a commercial product, without any examination. So I don't understand the premise of your question.

MP	My question is what I see here so often. I've seen so much over the years I've been here, since 1996, 97. That's the premise of it. On the basis, the place is invaded by industry and industry gets ahead [unclear]. And that has influence in all sorts of areas.

HF	Okay, I... Well I cannot dispute it, but I cannot accept it. Okay, [unclear] do we have time for one or two more quick questions?

MP	You've talked about Doctor Chan's assessment. Did you share her assessment that no amount of planning is going to change that, you said it was a serious impediment. Do you share her assessment?

HF I'm going to take it on board. That is, I'm going to try to understand the basis of her sentiment and think very carefully about what exactly could potentially have been done, even now, could be done, in advance of a next pandemic. The one thing that I would say this experience clearly demonstrated is, you cannot do very much when in the midst of the emergency. That was demonstrated by the experience. Now, the question, how much could be done in advance, the committees initial view was that you could do more. And I think we have to now think about it in light of that comment and see whether we agree or not.

MP And just, the report says... It came out a few weeks ago, so I apologise for not being completely familiar anymore, with the exact way you phrased the recommendation, in terms of the severity, re-doing the scale. What are your expectations in terms of when that should be... or the committee's expectations about when that should be out?

HF Well, I think, on the question of severity, we're... we recognise the difficulty and the complexity of the measurement. What we're saying is, first that the WHO has to face up to the need to report severity and to measure it at different stages. And I think there's not much disagreement about that, as expressed today. The tricky and difficult part will now be, okay, reduce that to actionable indicators. And that's going to take some time and continued effort. And it's not as if it's never been attempted before. But every pandemic experience gives you a better handle on how you might be able to do it. And that's what we want to take advantage of.

MP Do you have any time, does the committee...?

HF The committee didn't say it has to be done, you know, within a year or within six months or two years. But I do think that it's going to take months and probably the better part of a year or two, to really nail this down. That's my estimate, but that's not what the committee is specifying. It's not something you can just turn around and pull out of a drawer. Any final question? Well thank you all very much. Yes, you have...? All right, we almost got done. We'll take one more... a quick one.

MP Coming back to Doctor Chan's comments, she left no stone unturned to try and get the donated vaccines to countries that didn't have the capacity. Some industry representatives said to us that some of the donations were available months in advance to WHO and did not go out to the potential recipient States. Today's version, from Doctor Chan is another interpretation. What did your insights show?

HF Yes, first the companies differed in their willingness to enter agreements. There was some negotiation that was difficult, but concluded successfully. There was other that was relatively easy and there was some that never concluded. So on the question of the readiness of companies to participate, there was a spectrum. On the question of getting the vaccine actually into the hands of doctors, nurses and other administrators in the country, you have still all of these issues about the cold chain and about the regulations in the country and approvals locally that Doctor Chan also indicated were significant obstacles.

And so it's very easy to imagine the circumstance where a representative of a company that was readily, relatively willing to contribute, would find themselves in an observation of delay, because of these other factors that are country specific, in getting the vaccine out. So you can see how you could reconcile those perspectives on the question of getting the vaccine to the recipient countries. And it underscores the complexity of it. I would say it also underscores the importance of advance arrangements insofar as they can be accomplished. So, I think, with that I thank you all and I look forward perhaps to see some of you at the World Health Assembly, or no...

MP Of course.

HF Of course, and we'll see how the discussion is at that venue.

MP And useful from our point of view I think.

# Contents

**Transcript ... Dates** PDF pp.

Transcript of the 26 April 2009 press Conference, Keiji Fukuda ... 4
Transcript of the 27 April 2009 press Conference, Keiji Fukuda ... 16
Transcript of the 27 April 2009 press Conference, Gregory Hartl ... 25
Transcript of the 28 April 2009 press Conference, Keiji Fukuda ... 31
Transcript of the 29 April 2009 press Conference, Keiji Fukuda ... 40
Transcript of the 30 April 2009 press Conference, Keiji Fukuda ... 47
Transcript of the 1 May 2009 press Conference, Gregory Hartl, and Dr Marie-Paule Kieny 52
Transcript of the 2 May 2009 press Conference, Dick Thompson, and Dr Mike Ryan ... 54
Transcript of the 3 May 2009 press Conference, Gregory Hartl, and Dr Peter Ben Embarek ... 62
Transcript of the 4 May 2009 press Conference, Gregory Hartl, and Dr Keiji Fukuda ... 68
Transcript of the 5 May 2009 press Conference, Gregory Hartl, and Dr Keiji Fukuda ... 77
Transcript of the 6 May 2009 press Conference, Gregory Hartl, and Dr Marie-Paule Kieny, 86
Transcript of the 7 May 2009 press Conference, Gregory Hartl, and Dr Keiji Fukuda ... 96
Transcript of the 8 May 2009 press Conference, Gregory Hartl, and Dr Sylvie Briand ... 103
Transcript of the 11 May 2009 press Conference, Gregory Hartl, and Dr Keiji Fukuda ... 109
Transcript of the 12 May 2009 press Conference, Gregory Hartl, and Dr Nikki Shindo ... 118
Transcript of the 13 May 2009 press Conference, Gregory Hartl, and Dr Sylvie Briand ... 124
Transcript of the 14 May 2009 press Conference, Gregory Hartl, and Dr Keiji Fukuda ... 130
Transcript of the 22 May 2009 press Conference, Gregory Hartl, and Dr Keiji Fukuda ... 139
Transcript of the 26 May 2009 press Conference, Gregory Hartl, and Dr Keiji Fukuda ... 150
Transcript of the 2 June 2009 press Conference, Gregory Hartl, and Dr Keiji Fukuda ... 158
Transcript of the 9 June 2009 press Conference, Dick Thompson, and Dr Keiji Fukuda ... 165
Transcript of the 11 June 2009 press Conference, Margaret Chan, Director-General, WHO 173
Transcript of the 7 July 2009 press Conference, Dr Keiji Fukuda ... 181
Transcript of the 13 July 2009 press Conference, Gregory Hartl, and Dr Marie-Paule Kieny 187
Transcript of the 6 Aug. 2009 press Conference, Dr Marie-Paule Kieny and Gregory Hartl 195
Transcript of the 24 September 2009 press Conference, Dr Marie-Paule Kieny and Gregory Hartl 206
Transcript of the 30 October 2009 press Conference, Gregory Hartl and Dr Marie-Paule Kieny 214
Transcript of the 5 November 2009 press Conference, Gregory Hartl, and Dr Keiji Fukuda 222
Transcript of the 12 November 2009 press Conference, Gregory Hartl, and Dr Nikki Shindo 234
Transcript of the 19 November 2009 press Conference, Dr Marie-Paule Kieny ... 239
Transcript of the 26 November 2009 press Conference, Kristen Kelleher, Dr Keiji Fukuda... 244
Transcript of the 3 December 2009 press Conference, Dr Keiji Fukuda ... 251
Transcript of the 17 December 2009 press Conference, Dr Keiji Fukuda ... 258
Transcript of the 14 January 2010 press Conference, Dr Keiji Fukuda ... 266
Transcript of the 11 February 2010 press Conference, Dr Keiji Fukuda ... 279
Transcript of the 18 February 2010 press Conference, Dr Keiji Fukuda ... 291
Transcript of the 24 February 2010 press Conference, Dr Keiji Fukuda ... 300
Transcript of the 29 March 2010 press Conference, Dr Keiji Fukuda ... 312
Transcript of the 14 April 2010 press Conference, Dr Harvey Fineberg ... 324
Transcript of the 19 May 2010 press Conference, Dr Harvey Fineberg ... 339
Transcript of the 2 July 2010 press Conference, Dr Harvey Fineberg ... 351
Transcript of the 10 August 2010 press Conference, Dr Margaret Chan, Dr Keiji Fukuda ... 369
Transcript of the 29 September 2010 press Conference, Dr Harvey Fineberg ... 379
Transcript of the 11 March 2011 press Conference, Dr Harvey Fineberg ... 402